

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Bevacizumab gamma (Lytenava™)

Outlook Therapeutics Limited

Modul 4 A – Anhang 4-G

Erwachsene mit nAMD

Weitere Ergebnisse zu
RCT mit dem zu bewertenden Arzneimittel
NORSE TWO und NORSE ONE

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Table Morb_65

BCVA Change from Baseline - Trimmed Means Fixed Approach in NORSE-2 Study
(ITT Population)

Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
BCVA Score Change from Baseline to 11 Months [1]	n	96	104
	Mean (SD)	5.8 (14.80)	11.2 (12.19)
	Median	6.0	12.0
	Min, Max	-42, 42	-47, 40
LS Means [2]		14.575	19.310
LS Means Difference [2]			4.735
(95% CI)			(1.306, 8.163)
p-value			0.0035
Corrected Hedges' G (95% CI)			0.5616 (0.2788, 0.8445)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means fixed approach compares the 50% best (> median) observations in each treatment arm. Those observations with missing data at 11 months had values worse than the median imputed to calculate the adjusted median in which the best 50% were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportions of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by adding the 2.5 and 97.5 percentiles from the same permutation distribution to the observed LS Means Difference. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 7416.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] LS Means and difference estimated from ANCOVA model using the best 50% subset.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_65

DATE: 14MAY2024 12:59

Table Morb_66

BCVA Change from Baseline - Trimmed Means Adaptive Approach in NORSE-2 Study
(ITT Population)

Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
BCVA Score Change from Baseline to 11 Months [1]	n	96	104
	Mean (SD)	5.8 (14.80)	11.2 (12.19)
	Median	6.0	12.0
	Min, Max	-42, 42	-47, 40
LS Means [2]		6.260	13.652
LS Means Difference [2]			7.392
(95% CI)			(3.921, 11.825)
p-value			0.0002
Corrected Hedges' G (95% CI)			0.6150 (0.3311, 0.8989)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means adaptive approach assigns a percentile floor in the treatment arm based on the greatest proportion of dropouts observed between the two arms. Those observations with missing data at 11 months had values worse than the percentile floor imputed to calculate the adjusted floor in which the best observations were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by adding the 2.5 and 97.5 percentiles from the same permutation distribution to the observed LS Means Difference. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 4384.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] LS Means and difference estimated from ANCOVA model using the best 50% subset.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_66

DATE: 14MAY2024 13:00

Table Morb_67

BCVA Change from Baseline - Analysis of Covariance in NORSE-2 Study
(ITT Population)

Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
BCVA Score Change from Baseline to 11 Months [1]	n	96	104
	Mean (SD)	5.8 (14.80)	11.2 (12.19)
	Median	6.0	12.0
	Min, Max	-42, 42	-47, 40
LS Means (SE)		5.807 (1.3519)	11.226 (1.2989)
(95% CI)		(3.141, 8.473)	(8.665, 13.788)
LS Means Difference (SE)			5.419 (1.8748)
(95% CI)			(1.722, 9.117)
p-value [2]			0.0043
Corrected Hedges' G (95% CI)			0.4076 (0.1273, 0.6879)

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_67

DATE: 14MAY2024 13:01

Table Morb_68

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation in NORSE-2 Study
(ITT Population)

Parameter [1]	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
BCVA Score Change from Baseline to 11 Months [2]	n	96	104
	Mean (SD)	5.8 (14.80)	11.2 (12.19)
	Median	6.0	12.0
	Min, Max	-42, 42	-47, 40
LS Means (SE)		5.131 (1.3632)	11.191 (1.3112)
(95% CI)		(2.459, 7.803)	(8.621, 13.761)
LS Means Difference (SE)			6.060 (1.8927)
(95% CI)			(2.350, 9.770)
p-value [3]			0.0014
Corrected Hedges' G (95% CI)			0.4517 (0.1708, 0.7326)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_68

DATE: 14MAY2024 13:02

Table Morb_71

Subjects Gaining >=15 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Number of Subjects, n/N1 (%) [1]	17/ 49 (34.7)	29/ 60 (48.3)
	Odds Ratio [2]	1.7609	
	95% CI	(0.7575, 4.1316)	
	Relative Risk [2]	1.3931	
	95% CI	(0.8812, 2.5019)	
	Absolute Risk Reduction [2]	0.1364	
	95% CI	(-0.0532, 0.3163)	
	p-value [3]	0.1755	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_71

DATE: 11JUN2024 14:43

Table Morb_71

Subjects Gaining >=15 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Number of Subjects, n/N1 (%) [1]	7/ 55 (12.7)	16/ 48 (33.3)
	Odds Ratio [2] 95% CI	3.4286 (1.1602, 10.8958)	
	Relative Risk [2] 95% CI	2.6190 (1.1141, 7.1802)	
	Absolute Risk Reduction [2] 95% CI	0.2061 (0.0364, 0.3731)	
	p-value [3]	0.0172	
Interaction	p-value [4]	0.6742	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_71

DATE: 11JUN2024 14:43

Table Morb_71

Subjects Gaining >=15 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Number of Subjects, n/N (%) [1]	17/ 54 (31.5)	29/ 62 (46.8)
	Odds Ratio [2]	1.9127	
	95% CI	(0.8381, 4.4099)	
	Relative Risk [2]	1.4858	
	95% CI	(0.9270, 2.7018)	
	Absolute Risk Reduction [2]	0.1529	
	95% CI	(-0.0305, 0.3264)	
	p-value [3]	0.1278	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_71

DATE: 11JUN2024 14:43

Table Morb_71

Subjects Gaining >=15 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Number of Subjects, n/N (%) [1]	7/ 61 (11.5)	16/ 51 (31.4)
	Odds Ratio [2] 95% CI	3.5265 (1.2082, 11.0981)	
	Relative Risk [2] 95% CI	2.7339 (1.1336, 7.5684)	
	Absolute Risk Reduction [2] 95% CI	0.1990 (0.0361, 0.3563)	
	p-value [3]	0.0175	
Interaction	p-value [4]	0.7234	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_71

DATE: 11JUN2024 14:43

Table Morb_72

Subjects Gaining >=10 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Number of Subjects, n/N1 (%) [1]	21/ 49 (42.9)	37/ 60 (61.7)
	Odds Ratio [2]	2.1449	
	95% CI	(0.9289, 4.9718)	
	Relative Risk [2]	1.4389	
	95% CI	(0.9855, 2.2835)	
	Absolute Risk Reduction [2]	0.1881	
	95% CI	(-0.0080, 0.3692)	
	p-value [3]	0.0564	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_72

DATE: 11JUN2024 14:50

Table Morb_72

Subjects Gaining >=10 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Number of Subjects, n/N1 (%) [1]	15/ 55 (27.3)	24/ 48 (50.0)
	Odds Ratio [2] 95% CI	2.6667 (1.0895, 6.5877)	
	Relative Risk [2] 95% CI	1.8333 (1.0608, 3.4655)	
	Absolute Risk Reduction [2] 95% CI	0.2273 (0.0340, 0.4096)	
	p-value [3]	0.0249	
Interaction	p-value [4]	0.8642	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_72

DATE: 11JUN2024 14:50

Table Morb_72

Subjects Gaining >=10 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Number of Subjects, n/N (%) [1]	21/ 54 (38.9)	37/ 62 (59.7)
	Odds Ratio [2]	2.3257	
	95% CI	(1.0347,5.2528)	
	Relative Risk [2]	1.5346	
	95% CI	(1.0233,2.4698)	
	Absolute Risk Reduction [2]	0.2079	
	95% CI	(0.0176,0.3816)	
	p-value [3]	0.0401	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_72

DATE: 11JUN2024 14:50

Table Morb_72

Subjects Gaining >=10 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Number of Subjects, n/N (%) [1]	15/ 61 (24.6)	24/ 51 (47.1)
	Odds Ratio [2] 95% CI	2.7259 (1.1385, 6.5921)	
	Relative Risk [2] 95% CI	1.9137 (1.0835, 3.6703)	
	Absolute Risk Reduction [2] 95% CI	0.2247 (0.0359, 0.3982)	
	p-value [3]	0.0170	
Interaction	p-value [4]	0.9295	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_72

DATE: 11JUN2024 14:50

Table Morb_73

Subjects Gaining >=5 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Number of Subjects, n/N1 (%) [1]	27/ 49 (55.1)	45/ 60 (75.0)
	Odds Ratio [2]	2.4444	
	95% CI	(1.0077, 5.9788)	
	Relative Risk [2]	1.3611	
	95% CI	(1.0205, 1.9484)	
	Absolute Risk Reduction [2]	0.1990	
	95% CI	(0.0114, 0.3756)	
	p-value [3]	0.0416	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_73

DATE: 12JUN2024 4:40

Table Morb_73

Subjects Gaining >=5 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Number of Subjects, n/N1 (%) [1]	26/ 55 (47.3)	29/ 48 (60.4)
	Odds Ratio [2] 95% CI	1.7024 (0.7243, 4.0211)	
	Relative Risk [2] 95% CI	1.2780 (0.8769, 1.8764)	
	Absolute Risk Reduction [2] 95% CI	0.1314 (-0.0685, 0.3194)	
	p-value [3]	0.2354	
Interaction	p-value [4]	0.5532	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_73

DATE: 12JUN2024 4:40

Table Morb_73

Subjects Gaining >=5 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Number of Subjects, n/N (%) [1]	27/ 54 (50.0)	45/ 62 (72.6)
	Odds Ratio [2]	2.6471	
	95% CI	(1.1436, 6.1738)	
	Relative Risk [2]	1.4516	
	95% CI	(1.0538, 2.1124)	
	Absolute Risk Reduction [2]	0.2258	
	95% CI	(0.0360, 0.3977)	
	p-value [3]	0.0138	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_73

DATE: 12JUN2024 4:40

Table Morb_73

Subjects Gaining >=5 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Number of Subjects, n/N (%) [1]	26/ 61 (42.6)	29/ 51 (56.9)
	Odds Ratio [2] 95% CI	1.7745 (0.7840,4.0293)	
	Relative Risk [2] 95% CI	1.3341 (0.9018,1.9768)	
	Absolute Risk Reduction [2] 95% CI	0.1424 (-0.0494,0.3242)	
	p-value [3]	0.1839	
Interaction	p-value [4]	0.5061	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_73

DATE: 12JUN2024 4:40

Table Morb_74

Subjects Loosing < 15 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Number of Subjects, n/N1 (%) [1]	39/ 49 (79.6)	59/ 60 (98.3)
	Odds Ratio [2]	15.1282	
	95% CI	(1.9704, 667.3405)	
	Relative Risk [2]	1.2355	
	95% CI	(1.0769, 1.5050)	
	Absolute Risk Reduction [2]	0.1874	
	95% CI	(0.0698, 0.3277)	
	p-value [3]	0.0023	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_74

DATE: 12JUN2024 4:43

Table Morb_74

Subjects Loosing < 15 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Number of Subjects, n/N1 (%) [1]	47/ 55 (85.5)	42/ 48 (87.5)
	Odds Ratio [2] 95% CI	1.1915 (0.3306, 4.5258)	
	Relative Risk [2] 95% CI	1.0239 (0.8562, 1.2200)	
	Absolute Risk Reduction [2] 95% CI	0.0205 (-0.1263, 0.1644)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.0561	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_74

DATE: 12JUN2024 4:43

Table Morb_74

Subjects Loosing < 15 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Number of Subjects, n/N (%) [1]	39/ 54 (72.2)	59/ 62 (95.2)
	Odds Ratio [2]	7.5641	
	95% CI	(1.9263, 42.7036)	
	Relative Risk [2]	1.3176	
	95% CI	(1.1020, 1.6508)	
	Absolute Risk Reduction [2]	0.2294	
	95% CI	(0.0781, 0.3715)	
	p-value [3]	0.0007	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_74

DATE: 12JUN2024 4:43

Table Morb_74

Subjects Loosing < 15 Letters from Baseline to 11 Months by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Number of Subjects, n/N (%) [1]	47/ 61 (77.0)	42/ 51 (82.4)
	Odds Ratio [2] 95% CI	1.3901 (0.4983, 4.0343)	
	Relative Risk [2] 95% CI	1.0688 (0.8653, 1.3081)	
	Absolute Risk Reduction [2] 95% CI	0.0530 (-0.1069, 0.2048)	
	p-value [3]	0.6393	
Interaction	p-value [4]	0.0792	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_74

DATE: 12JUN2024 4:43

Table Morb_75

BCVA Change from Baseline - Trimmed Means Fixed Approach by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	BCVA Score Change from Baseline to 11 Months [1]	n	44	59
		Mean (SD)	9.0 (16.68)	13.0 (11.01)
		Median	9.0	13.0
		Min, Max	-42, 42	-11, 40
		LS Means [2]	18.873	21.078
		LS Means Difference [2] (95% CI)		2.206 (-2.011, 6.597)
		p-value		0.1692
		Corrected Hedges' G (95% CI)		0.2696 (-0.1226, 0.6618)
≥ 80 years	BCVA Score Change from Baseline to 11 Months [1]	n	52	45
		Mean (SD)	3.1 (12.54)	8.9 (13.35)
		Median	4.5	10.0
		Min, Max	-29, 24	-47, 31
		LS Means [2]	10.821	16.482
		LS Means Difference [2] (95% CI)		5.661 (1.244, 9.918)
		p-value		0.0041
		Corrected Hedges' G (95% CI)		0.8305 (0.4145, 1.2466)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means fixed approach compares the 50% best (> median) observations in each treatment arm. Those observations with missing data at 11 months had values worse than the median imputed to calculate the adjusted median in which the best 50% were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportions of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by adding the 2.5 and 97.5 percentiles from the same permutation distribution to the observed LS Means Difference. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 7416.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] LS Means and difference estimated from ANCOVA model using the best 50% subset.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_75

DATE: 15MAY2024 13:14

Table Morb_76
BCVA Change from Baseline - Trimmed Means Adaptive Approach by Age Group in NORSE-2 Study (ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	BCVA Score Change from Baseline to 11 Months [1]	n	44	59
		Mean (SD)	9.0 (16.68)	13.0 (11.01)
		Median	9.0	13.0
		Min, Max	-42, 42	-11, 40
	LS Means [2]		8.729	15.724
	LS Means Difference [2]			6.995
	(95% CI)			(2.219, 12.963)
	p-value			0.0094
	Corrected Hedges' G (95% CI)			0.5155 (0.1187, 0.9123)
≥ 80 years	BCVA Score Change from Baseline to 11 Months [1]	n	52	45
		Mean (SD)	3.1 (12.54)	8.9 (13.35)
		Median	4.5	10.0
		Min, Max	-29, 24	-47, 31
	LS Means [2]		3.773	10.081
	LS Means Difference [2]			6.307
	(95% CI)			(1.518, 12.616)
	p-value			0.0250
	Corrected Hedges' G (95% CI)			0.5734 (0.1661, 0.9806)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means adaptive approach assigns a percentile floor in the treatment arm based on the greatest proportion of dropouts observed between the two arms. Those observations with missing data at 11 months had values worse than the percentile floor imputed to calculate the adjusted floor in which the best observations were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by adding the 2.5 and 97.5 percentiles from the same permutation distribution to the observed LS Means Difference. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 4384.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] LS Means and difference estimated from ANCOVA model using the best 50% subset.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_76

DATE: 16MAY2024 4:12

Table Morb_77

BCVA Change from Baseline - Analysis of Covariance by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	BCVA Score Change from Baseline to 11 Months [1]	n	44	59
		Mean (SD)	9.0 (16.68)	13.0 (11.01)
		Median	9.0	13.0
		Min, Max	-42, 42	-11, 40
		LS Means (SE)	8.941 (2.0468)	13.044 (1.7675)
		(95% CI)	(4.880, 13.002)	(9.537, 16.551)
		LS Means Difference (SE)		4.103 (2.7045)
		(95% CI)		(-1.262, 9.469)
≥ 80 years	BCVA Score Change from Baseline to 11 Months [1]	p-value [2]		0.1323
		Corrected Hedges' G (95% CI)		0.3000 (-0.0926, 0.6926)
		n	52	45
		Mean (SD)	3.1 (12.54)	8.9 (13.35)
		Median	4.5	10.0
		Min, Max	-29, 24	-47, 31
		LS Means (SE)	3.156 (1.7460)	8.841 (1.8769)
		(95% CI)	(-0.310, 6.623)	(5.115, 12.568)
		LS Means Difference (SE)		5.685 (2.5635)
		(95% CI)		(0.595, 10.775)
		p-value [2]		0.0290
		Corrected Hedges' G (95% CI)		0.4480 (0.0439, 0.8520)

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_77

DATE: 16MAY2024 9:56

Table Morb_78

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter [1]	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	BCVA Score Change from Baseline to 11 Months [2]	n	44	59
		Mean (SD)	9.0 (16.68)	13.0 (11.01)
		Median	9.0	13.0
		Min, Max	-42, 42	-11, 40
		LS Means (SE)	7.351 (2.0866)	13.038 (1.8529)
		(95% CI)	(3.260, 11.441)	(9.406, 16.669)
		LS Means Difference (SE)		5.687 (2.7960)
		(95% CI)		(0.207, 11.167)
	p-value [3]			0.0420
	Corrected Hedges' G (95% CI)			0.4013 (0.0070, 0.7956)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_78

DATE: 16MAY2024 5:07

Table Morb_78

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Parameter [1]	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	BCVA Score Change from Baseline to 11 Months [2]	n	52	45
		Mean (SD)	3.1 (12.54)	8.9 (13.35)
		Median	4.5	10.0
		Min, Max	-29, 24	-47, 31
	LS Means (SE)		3.192 (1.7382)	8.915 (1.8325)
	(95% CI)		(-0.216, 6.599)	(5.323, 12.507)
	LS Means Difference (SE)			5.723 (2.5174)
	(95% CI)			(0.789, 10.658)
	p-value [3]			0.0230
	Corrected Hedges' G (95% CI)			0.4570 (0.0528, 0.8613)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_78

DATE: 16MAY2024 5:07

Table Morb_79

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Day 30	BCVA Score Change from Baseline	n	51	60
			Mean (SD)	7.6 (8.92)	7.9 (8.61)
			Median	7.0	7.0
			Min, Max	-8, 40	-11, 32
		LS Means (SE) [1]		7.935 (1.8613)	7.582 (1.7071)
		(95% CI)		(4.257, 11.612)	(4.208, 10.955)
		LS Means Difference (SE)			-0.353 (2.5256)
		(95% CI)			(-5.343, 4.637)
< 80 years	Day 60		p-value		0.8890
		Corrected Hedges' G (95% CI)			-0.0265 (-0.3998, 0.3469)
		BCVA Score Change from Baseline	n	49	58
			Mean (SD)	7.6 (11.20)	9.7 (8.61)
			Median	6.0	9.0
			Min, Max	-29, 34	-10, 34
		LS Means (SE) [1]		8.725 (1.7170)	9.494 (1.5731)
		(95% CI)		(5.331, 12.119)	(6.385, 12.604)
		LS Means Difference (SE)			0.769 (2.3287)
		(95% CI)			(-3.834, 5.372)
		p-value			0.7417
		Corrected Hedges' G (95% CI)			0.0636 (-0.3168, 0.4441)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_79

DATE: 16MAY2024 10:41

Table Morb_79

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Day 90	BCVA Score Change from Baseline	n	51	58
			Mean (SD)	9.6 (11.80)	10.6 (9.57)
			Median	10.0	10.0
			Min, Max	-26, 42	-6, 32
		LS Means (SE) [1]		9.434 (1.6385)	10.182 (1.5051)
		(95% CI)		(6.191, 12.677)	(7.203, 13.160)
		LS Means Difference (SE)			0.748 (2.2248)
		(95% CI)			(-3.656, 5.151)
< 80 years	Day 120		p-value		0.7374
		Corrected Hedges' G (95% CI)			0.0641 (-0.3122, 0.4405)
		BCVA Score Change from Baseline	n	48	57
			Mean (SD)	9.7 (11.41)	11.5 (9.92)
			Median	10.0	13.0
			Min, Max	-11, 34	-8, 36
		LS Means (SE) [1]		8.696 (1.6651)	10.932 (1.5265)
		(95% CI)		(5.402, 11.990)	(7.912, 13.952)
		LS Means Difference (SE)			2.236 (2.2589)
		(95% CI)			(-2.233, 6.705)
		p-value			0.3241
		Corrected Hedges' G (95% CI)			0.1925 (-0.1924, 0.5774)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_79

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Day 150	BCVA Score Change from Baseline	n	46	59
			Mean (SD)	7.6 (12.91)	11.0 (11.03)
			Median	8.5	10.0
			Min, Max	-30, 34	-13, 34
		LS Means (SE) [1]		6.389 (1.7247)	10.987 (1.5715)
		(95% CI)		(2.980, 9.798)	(7.880, 14.094)
		LS Means Difference (SE)			4.598 (2.3333)
		(95% CI)			(-0.014, 9.211)
< 80 years	Day 180		p-value		0.0507
		Corrected Hedges' G (95% CI)			0.3833 (-0.0057, 0.7723)
		BCVA Score Change from Baseline	n	43	59
			Mean (SD)	10.4 (12.91)	11.7 (11.57)
			Median	12.0	14.0
			Min, Max	-39, 36	-20, 37
		LS Means (SE) [1]		7.538 (1.7618)	11.623 (1.5916)
		(95% CI)		(4.058, 11.018)	(8.478, 14.768)
		LS Means Difference (SE)			4.085 (2.3742)
		(95% CI)			(-0.605, 8.776)
		p-value			0.0873
		Corrected Hedges' G (95% CI)			0.3394 (-0.0564, 0.7352)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_79

DATE: 16MAY2024 10:41

Table Morb_79

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Day 210	BCVA Score Change from Baseline	n	45	56
			Mean (SD)	9.0 (14.35)	12.6 (10.91)
			Median	11.0	13.0
			Min, Max	-37, 36	-17, 37
		LS Means (SE) [1]		8.039 (1.8176)	12.651 (1.6467)
		(95% CI)		(4.450, 11.629)	(9.399, 15.904)
		LS Means Difference (SE)			4.612 (2.4526)
		(95% CI)			(-0.232, 9.456)
< 80 years	Day 240		p-value		0.0619
		Corrected Hedges' G (95% CI)			0.3732 (-0.0226, 0.7690)
		BCVA Score Change from Baseline	n	42	57
			Mean (SD)	7.8 (16.14)	12.4 (10.42)
			Median	10.5	11.0
			Min, Max	-44, 34	-15, 39
		LS Means (SE) [1]		6.610 (1.7417)	12.160 (1.5694)
		(95% CI)		(3.169, 10.051)	(9.059, 15.262)
		LS Means Difference (SE)			5.550 (2.3444)
		(95% CI)			(0.918, 10.183)
		p-value			0.0192
		Corrected Hedges' G (95% CI)			0.4742 (0.0701, 0.8783)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_79

DATE: 16MAY2024 10:41

Table Morb_79

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Day 270	BCVA Score Change from Baseline	n	44	57
			Mean (SD)	10.4 (16.16)	12.0 (10.81)
			Median	12.5	12.0
			Min, Max	-43, 40	-17, 38
		LS Means (SE) [1]		8.824 (1.7335)	12.011 (1.5666)
		(95% CI)		(5.400, 12.249)	(8.915, 15.106)
		LS Means Difference (SE)			3.186 (2.3366)
		(95% CI)			(-1.430, 7.802)
< 80 years	Day 300		p-value		0.1747
		Corrected Hedges' G (95% CI)			0.2706 (-0.1245, 0.6657)
		BCVA Score Change from Baseline	n	41	58
			Mean (SD)	8.4 (17.59)	12.6 (10.34)
			Median	10.0	13.0
			Min, Max	-37, 41	-16, 38
		LS Means (SE) [1]		7.594 (1.8801)	12.497 (1.6777)
		(95% CI)		(3.885, 11.304)	(9.186, 15.809)
		LS Means Difference (SE)			4.903 (2.5198)
		(95% CI)			(-0.070, 9.876)
		p-value			0.0533
		Corrected Hedges' G (95% CI)			0.3899 (-0.0137, 0.7935)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_79

DATE: 16MAY2024 10:41

Table Morb_79

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Best Case to MONTH 11	BCVA Score Change from Baseline	n	44	59
			Mean (SD)	9.0 (16.68)	13.0 (11.01)
			Median	9.0	13.0
			Min, Max	-42, 42	-11, 40
		LS Means (SE) [1]		8.114 (1.7605)	12.974 (1.5816)
		(95% CI)		(4.638, 11.590)	(9.850, 16.099)
		LS Means Difference (SE)			4.861 (2.3666)
		(95% CI)			(0.187, 9.534)
		p-value			0.0416
		Corrected Hedges' G (95% CI)			0.4037 (0.0094, 0.7980)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_79

DATE: 16MAY2024 10:41

Table Morb_79

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Day 30	BCVA Score Change from Baseline	n	56	51
			Mean (SD)	4.4 (8.64)	4.2 (7.86)
			Median	3.0	3.0
			Min, Max	-22, 28	-27, 23
		LS Means (SE) [1]		4.221 (1.7371)	4.216 (1.8504)
		(95% CI)		(0.792, 7.649)	(0.563, 7.868)
		LS Means Difference (SE)			-0.005 (2.5380)
		(95% CI)			(-5.015, 5.005)
≥ 80 years	Day 60	BCVA Score Change from Baseline	n	56	49
			Mean (SD)	5.6 (10.12)	5.2 (11.40)
			Median	6.0	5.0
			Min, Max	-20, 36	-44, 27
		LS Means (SE) [1]		5.375 (1.5626)	4.947 (1.6790)
		(95% CI)		(2.286, 8.463)	(1.629, 8.266)
		LS Means Difference (SE)			-0.427 (2.2936)
		(95% CI)			(-4.961, 4.106)
		p-value			0.9984
		Corrected Hedges' G (95% CI)			-0.0004 (-0.3798, 0.3790)
		p-value			0.8524
		Corrected Hedges' G (95% CI)			-0.0362 (-0.4196, 0.3472)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_79

DATE: 16MAY2024 10:41

Table Morb_79

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Day 90	BCVA Score Change from Baseline	n	55	49
			Mean (SD)	6.5 (11.50)	7.6 (11.72)
			Median	8.0	9.0
			Min, Max	-25, 36	-46, 29
		LS Means (SE) [1]		6.205 (1.5572)	7.335 (1.6679)
		(95% CI)		(3.127, 9.283)	(4.038, 10.632)
		LS Means Difference (SE)			1.130 (2.2819)
		(95% CI)			(-3.380, 5.641)
≥ 80 years	Day 120	BCVA Score Change from Baseline	n	56	47
			Mean (SD)	6.9 (10.97)	6.2 (11.92)
			Median	6.5	6.0
			Min, Max	-19, 40	-46, 26
		LS Means (SE) [1]		6.787 (1.5642)	6.255 (1.6881)
		(95% CI)		(3.696, 9.879)	(2.919, 9.591)
		LS Means Difference (SE)			-0.532 (2.3014)
		(95% CI)			(-5.081, 4.016)
		p-value			0.6211
		Corrected Hedges' G (95% CI)			0.0967 (-0.2886, 0.4819)
		p-value			0.8174
		Corrected Hedges' G (95% CI)			-0.0454 (-0.4331, 0.3424)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_79

DATE: 16MAY2024 10:41

Table Morb_79

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Day 150	BCVA Score Change from Baseline	n	50	47
			Mean (SD)	3.3 (11.52)	7.6 (12.49)
			Median	4.0	9.0
			Min, Max	-27, 32	-46, 29
		LS Means (SE) [1]		3.234 (1.5091)	7.515 (1.6117)
		(95% CI)		(0.250, 6.219)	(4.327, 10.703)
		LS Means Difference (SE)			4.281 (2.2079)
		(95% CI)			(-0.086, 8.648)
≥ 80 years	Day 180	BCVA Score Change from Baseline	n	52	47
			Mean (SD)	4.2 (12.64)	7.6 (13.77)
			Median	5.0	7.0
			Min, Max	-29, 36	-51, 36
		LS Means (SE) [1]		4.264 (1.5469)	7.515 (1.6556)
		(95% CI)		(1.207, 7.321)	(4.243, 10.787)
		LS Means Difference (SE)			3.251 (2.2658)
		(95% CI)			(-1.227, 7.729)
		p-value			0.0546
		Corrected Hedges' G (95% CI)			0.3912 (-0.0108, 0.7933)
		p-value			0.1535
		Corrected Hedges' G (95% CI)			0.2868 (-0.1098, 0.6833)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_79

DATE: 16MAY2024 10:41

Table Morb_79

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Day 210	BCVA Score Change from Baseline	n	50	44
			Mean (SD)	4.2 (12.00)	5.3 (15.19)
			Median	4.5	4.5
			Min, Max	-26, 36	-46, 43
		LS Means (SE) [1]		3.963 (1.6286)	5.932 (1.7467)
		(95% CI)		(0.748, 7.179)	(2.483, 9.381)
		LS Means Difference (SE)			1.969 (2.3882)
		(95% CI)			(-2.746, 6.684)
≥ 80 years	Day 240	BCVA Score Change from Baseline	n	52	45
			Mean (SD)	2.5 (12.48)	6.2 (15.02)
			Median	4.0	7.0
			Min, Max	-30, 29	-46, 39
		LS Means (SE) [1]		2.507 (1.6409)	6.548 (1.7641)
		(95% CI)		(-0.732, 5.747)	(3.065, 10.030)
		LS Means Difference (SE)			4.040 (2.4093)
		(95% CI)			(-0.716, 8.796)
		p-value			0.4109
		Corrected Hedges' G (95% CI)			0.1691 (-0.2368, 0.5750)
		p-value			0.0954
		Corrected Hedges' G (95% CI)			0.3387 (-0.0632, 0.7407)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_79

DATE: 16MAY2024 10:41

Table Morb_79

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Day 270	BCVA Score Change from Baseline	n	52	42
			Mean (SD)	3.5 (12.40)	9.0 (13.50)
			Median	5.5	9.0
			Min, Max	-30, 32	-46, 42
		LS Means (SE) [1]		3.548 (1.5710)	8.553 (1.7026)
		(95% CI)		(0.444, 6.651)	(5.189, 11.916)
		LS Means Difference (SE)			5.005 (2.3167)
		(95% CI)			(0.428, 9.582)
≥ 80 years	Day 300	BCVA Score Change from Baseline	n	51	43
			Mean (SD)	5.1 (13.04)	7.7 (13.34)
			Median	6.0	8.0
			Min, Max	-31, 32	-46, 41
		LS Means (SE) [1]		5.131 (1.6786)	7.543 (1.8122)
		(95% CI)		(1.818, 8.444)	(3.966, 11.120)
		LS Means Difference (SE)			2.412 (2.4702)
		(95% CI)			(-2.464, 7.288)
		p-value			0.0323
		Corrected Hedges' G (95% CI)			0.4433 (0.0317, 0.8549)
		p-value			0.3302
		Corrected Hedges' G (95% CI)			0.2004 (-0.2065, 0.6072)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_79

DATE: 16MAY2024 10:41

Table Morb_79

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Best Case to MONTH 11	BCVA Score Change from Baseline	n	52	45
			Mean (SD)	3.1 (12.54)	8.9 (13.35)
			Median	4.5	10.0
			Min, Max	-29, 24	-47, 31
		LS Means (SE) [1]		3.089 (1.6795)	8.747 (1.8054)
		(95% CI)		(-0.225, 6.404)	(5.184, 12.310)
		LS Means Difference (SE)			5.658 (2.4657)
		(95% CI)			(0.791, 10.524)
		p-value			0.0230
		Corrected Hedges' G (95% CI)			0.4635 (0.0590, 0.8679)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_79

DATE: 16MAY2024 10:41

Table Morb_80

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Age Group in NORSE-2 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Number of Subjects, n/N1 (%) [1]	14/ 49 (28.6)	6/ 60 (10.0)
	Odds Ratio [2] 95% CI	0.2778 (0.0806, 0.8687)	
	Relative Risk [2] 95% CI	0.3500 (0.1040, 0.8943)	
	Absolute Risk Reduction [2] 95% CI	-0.1857 (-0.3434, -0.0349)	
	p-value [3]	0.0235	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_80

DATE: 12JUN2024 4:49

Table Morb_80

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Age Group in
NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Number of Subjects, n/N1 (%) [1]	11/ 55 (20.0)	8/ 48 (16.7)
	Odds Ratio [2]	0.8000	
	95% CI	(0.2523, 2.4447)	
	Relative Risk [2]	0.8333	
	95% CI	(0.3386, 1.9104)	
	Absolute Risk Reduction [2]	-0.0333	
	95% CI	(-0.1863, 0.1263)	
	p-value [3]	0.8003	
Interaction	p-value [4]	0.1417	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_80

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Age Group in
NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
< 80 years	Number of Subjects, n/N (%) [1]	14/ 54 (25.9)	6/ 62 (9.7)
	Odds Ratio [2] 95% CI	0.3061 (0.0894, 0.9471)	
	Relative Risk [2] 95% CI	0.3733 (0.1097, 0.9365)	
	Absolute Risk Reduction [2] 95% CI	-0.1625 (-0.3118, -0.0180)	
	p-value [3]	0.0268	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_80

DATE: 12JUN2024 4:49

Table Morb_80

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Age Group in
NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
≥ 80 years	Number of Subjects, n/N (%) [1]	11/ 61 (18.0)	8/ 51 (15.7)
	Odds Ratio [2]	0.8457	
	95% CI	(0.2691, 2.5570)	
	Relative Risk [2]	0.8699	
	95% CI	(0.3523, 2.0086)	
	Absolute Risk Reduction [2]	-0.0235	
	95% CI	(-0.1661, 0.1250)	
	p-value [3]	0.8045	
Interaction	p-value [4]	0.1565	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_81

Subjects Gaining >=15 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Number of Subjects, n/N1 (%) [1]	10/ 42 (23.8)	13/ 43 (30.2)
	Odds Ratio [2]	1.3867	
	95% CI	(0.4768, 4.1043)	
	Relative Risk [2]	1.2698	
	95% CI	(0.6137, 3.0025)	
	Absolute Risk Reduction [2]	0.0642	
	95% CI	(-0.1301, 0.2563)	
	p-value [3]	0.6267	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_81

DATE: 12JUN2024 4:53

Table Morb_81

Subjects Gaining >=15 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Number of Subjects, n/N1 (%) [1]	14/ 62 (22.6)	32/ 65 (49.2)
	Odds Ratio [2]	3.3247	
	95% CI	(1.4494, 7.7817)	
	Relative Risk [2]	2.1802	
	95% CI	(1.2649, 4.0962)	
	Absolute Risk Reduction [2]	0.2665	
	95% CI	(0.0788, 0.4241)	
	p-value [3]	0.0029	
Interaction	p-value [4]	0.0365	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_81

Subjects Gaining >=15 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Number of Subjects, n/N (%) [1]	10/ 46 (21.7)	13/ 46 (28.3)
	Odds Ratio [2]	1.4182	
	95% CI	(0.4952, 4.1363)	
	Relative Risk [2]	1.3000	
	95% CI	(0.6270, 3.1190)	
	Absolute Risk Reduction [2]	0.0652	
	95% CI	(-0.1165, 0.2473)	
	p-value [3]	0.6308	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_81

DATE: 12JUN2024 4:53

Table Morb_81

Subjects Gaining >=15 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Number of Subjects, n/N (%) [1]	14/ 69 (20.3)	32/ 67 (47.8)
	Odds Ratio [2]	3.5918	
	95% CI	(1.5867, 8.3051)	
	Relative Risk [2]	2.3539	
	95% CI	(1.3567, 4.4669)	
	Absolute Risk Reduction [2]	0.2747	
	95% CI	(0.1038, 0.4273)	
	p-value [3]	0.0010	
Interaction	p-value [4]	0.0255	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_82

Subjects Gaining ≥ 10 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Number of Subjects, n/N1 (%) [1]	16/ 42 (38.1)	20/ 43 (46.5)
	Odds Ratio [2]	1.4130	
	95% CI	(0.5465, 3.6700)	
	Relative Risk [2]	1.2209	
	95% CI	(0.7223, 2.1180)	
	Absolute Risk Reduction [2]	0.0842	
	95% CI	(-0.1296, 0.2942)	
	p-value [3]	0.5123	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_82

DATE: 12JUN2024 4:58

Table Morb_82

Subjects Gaining ≥ 10 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Number of Subjects, n/N1 (%) [1]	20/ 62 (32.3)	41/ 65 (63.1)
	Odds Ratio [2]	3.5875	
	95% CI	(1.6228, 7.9852)	
	Relative Risk [2]	1.9554	
	95% CI	(1.2875, 3.1198)	
	Absolute Risk Reduction [2]	0.3082	
	95% CI	(0.1166, 0.4701)	
	p-value [3]	0.0007	
Interaction	p-value [4]	0.0272	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_82

DATE: 12JUN2024 4:58

Table Morb_82

Subjects Gaining ≥ 10 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Number of Subjects, n/N (%) [1]	16/ 46 (34.8)	20/ 46 (43.5)
	Odds Ratio [2]	1.4423	
	95% CI	(0.5731, 3.6478)	
	Relative Risk [2]	1.2500	
	95% CI	(0.7251, 2.2024)	
	Absolute Risk Reduction [2]	0.0870	
	95% CI	(-0.1160, 0.2852)	
	p-value [3]	0.5219	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_82

DATE: 12JUN2024 4:58

Table Morb_82

Subjects Gaining ≥ 10 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Number of Subjects, n/N (%) [1]	20/ 69 (29.0)	41/ 67 (61.2)
	Odds Ratio [2]	3.8635	
	95% CI	(1.7838, 8.4279)	
	Relative Risk [2]	2.1112	
	95% CI	(1.3796, 3.4073)	
	Absolute Risk Reduction [2]	0.3221	
	95% CI	(0.1387, 0.4755)	
	p-value [3]	0.0003	
Interaction	p-value [4]	0.0173	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_83

Subjects Gaining >=5 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Number of Subjects, n/N1 (%) [1]	22/ 42 (52.4)	26/ 43 (60.5)
	Odds Ratio [2]	1.3904	
	95% CI	(0.5398, 3.5915)	
	Relative Risk [2]	1.1543	
	95% CI	(0.7851, 1.7399)	
	Absolute Risk Reduction [2]	0.0808	
	95% CI	(-0.1359, 0.2906)	
	p-value [3]	0.5151	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_83

DATE: 12JUN2024 5:02

Table Morb_83

Subjects Gaining >=5 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Number of Subjects, n/N1 (%) [1]	31/ 62 (50.0)	48/ 65 (73.8)
	Odds Ratio [2]	2.8235	
	95% CI	(1.2617, 6.3850)	
	Relative Risk [2]	1.4769	
	95% CI	(1.0722, 2.0480)	
	Absolute Risk Reduction [2]	0.2385	
	95% CI	(0.0538, 0.3998)	
	p-value [3]	0.0064	
Interaction	p-value [4]	0.0990	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_83

Subjects Gaining >=5 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Number of Subjects, n/N (%) [1]	22/ 46 (47.8)	26/ 46 (56.5)
	Odds Ratio [2]	1.4182	
	95% CI	(0.5769, 3.4951)	
	Relative Risk [2]	1.1818	
	95% CI	(0.7907, 1.8203)	
	Absolute Risk Reduction [2]	0.0870	
	95% CI	(-0.1245, 0.2929)	
	p-value [3]	0.5315	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_83

DATE: 12JUN2024 5:02

Table Morb_83

Subjects Gaining >=5 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Number of Subjects, n/N (%) [1]	31/ 69 (44.9)	48/ 67 (71.6)
	Odds Ratio [2]	3.0968	
	95% CI	(1.4358, 6.7381)	
	Relative Risk [2]	1.5946	
	95% CI	(1.1456, 2.2421)	
	Absolute Risk Reduction [2]	0.2671	
	95% CI	(0.0808, 0.4243)	
	p-value [3]	0.0018	
Interaction	p-value [4]	0.0606	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_84

Subjects Loosing < 15 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Number of Subjects, n/N1 (%) [1]	35/ 42 (83.3)	39/ 43 (90.7)
	Odds Ratio [2]	1.9500	
	95% CI	(0.4467, 9.8049)	
	Relative Risk [2]	1.0884	
	95% CI	(0.9044, 1.3431)	
	Absolute Risk Reduction [2]	0.0736	
	95% CI	(-0.0776, 0.2326)	
	p-value [3]	0.3512	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_84

DATE: 12JUN2024 5:27

Table Morb_84

Subjects Loosing < 15 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Number of Subjects, n/N1 (%) [1]	51/ 62 (82.3)	62/ 65 (95.4)
	Odds Ratio [2]	4.4575	
	95% CI	(1.0860, 25.9209)	
	Relative Risk [2]	1.1596	
	95% CI	(1.0242, 1.3705)	
	Absolute Risk Reduction [2]	0.1313	
	95% CI	(0.0215, 0.2538)	
	p-value [3]	0.0232	
Interaction	p-value [4]	0.2680	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_84

Subjects Loosing < 15 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Number of Subjects, n/N (%) [1]	35/ 46 (76.1)	39/ 46 (84.8)
	Odds Ratio [2]	1.7510	
	95% CI	(0.5454, 5.9231)	
	Relative Risk [2]	1.1143	
	95% CI	(0.9016, 1.4239)	
	Absolute Risk Reduction [2]	0.0870	
	95% CI	(-0.0844, 0.2541)	
	p-value [3]	0.4311	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_84

DATE: 12JUN2024 5:27

Table Morb_84

Subjects Loosing < 15 Letters from Baseline to 11 Months by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Number of Subjects, n/N (%) [1]	51/ 69 (73.9)	62/ 67 (92.5)
	Odds Ratio [2]	4.3765	
	95% CI	(1.4218, 15.9778)	
	Relative Risk [2]	1.2520	
	95% CI	(1.0628, 1.5161)	
	Absolute Risk Reduction [2]	0.1862	
	95% CI	(0.0493, 0.3164)	
	p-value [3]	0.0053	
Interaction	p-value [4]	0.1388	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_84

DATE: 12JUN2024 5:27

Table Morb_85

BCVA Change from Baseline - Trimmed Means Fixed Approach by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	BCVA Score Change from Baseline to 11 Months [1]	n	40	41
		Mean (SD)	4.7 (15.49)	9.6 (9.31)
		Median	6.5	8.0
		Min, Max	-42, 34	-17, 30
	LS Means [2]		14.935	15.630
	LS Means Difference [2] (95% CI)			0.696 (-4.173, 5.496)
	p-value			0.3936
	Corrected Hedges' G (95% CI)			0.0871 (-0.3487, 0.5229)
Female	BCVA Score Change from Baseline to 11 Months [1]	n	56	63
		Mean (SD)	6.6 (14.37)	12.3 (13.72)
		Median	6.0	15.0
		Min, Max	-37, 42	-47, 40
	LS Means [2]		14.056	21.296
	LS Means Difference [2] (95% CI)			7.240 (2.492, 12.039)
	p-value			0.0013
	Corrected Hedges' G (95% CI)			0.8345 (0.4591, 1.2100)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means fixed approach compares the 50% best (> median) observations in each treatment arm. Those observations with missing data at 11 months had values worse than the median imputed to calculate the adjusted median in which the best 50% were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportions of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by adding the 2.5 and 97.5 percentiles from the same permutation distribution to the observed LS Means Difference. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 7416.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] LS Means and difference estimated from ANCOVA model using the best 50% subset.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_85

DATE: 15MAY2024 13:22

Table Morb_86
BCVA Change from Baseline - Trimmed Means Adaptive Approach by Gender in NORSE-2 Study (ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	BCVA Score Change from Baseline to 11 Months [1]	n	40	41
		Mean (SD)	4.7 (15.49)	9.6 (9.31)
		Median	6.5	8.0
		Min, Max	-42, 34	-17, 30
	LS Means [2]		4.660	9.673
	LS Means Difference [2]			5.013
	(95% CI)			(-0.380, 11.585)
	p-value			0.0743
	Corrected Hedges' G (95% CI)			0.3933 (-0.0466, 0.8332)
Female	BCVA Score Change from Baseline to 11 Months [1]	n	56	63
		Mean (SD)	6.6 (14.37)	12.3 (13.72)
		Median	6.0	15.0
		Min, Max	-37, 42	-47, 40
	LS Means [2]		6.612	15.686
	LS Means Difference [2]			9.073
	(95% CI)			(4.317, 15.108)
	p-value			0.0006
	Corrected Hedges' G (95% CI)			0.7334 (0.3614, 1.1054)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means adaptive approach assigns a percentile floor in the treatment arm based on the greatest proportion of dropouts observed between the two arms. Those observations with missing data at 11 months had values worse than the percentile floor imputed to calculate the adjusted floor in which the best observations were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by adding the 2.5 and 97.5 percentiles from the same permutation distribution to the observed LS Means Difference. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 4384.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] LS Means and difference estimated from ANCOVA model using the best 50% subset.

Reference Listing: 16.2.6.1

Table Morb_87

BCVA Change from Baseline - Analysis of Covariance by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	BCVA Score Change from Baseline to 11 Months [1]	n	40	41
		Mean (SD)	4.7 (15.49)	9.6 (9.31)
		Median	6.5	8.0
		Min, Max	-42, 34	-17, 30
	LS Means (SE)		4.660 (1.9959)	9.673 (1.9714)
	(95% CI)		(0.687, 8.634)	(5.748, 13.598)
	LS Means Difference (SE)			5.013 (2.8056)
	(95% CI)			(-0.573, 10.598)
Female	BCVA Score Change from Baseline to 11 Months [1]	n	56	63
		Mean (SD)	6.6 (14.37)	12.3 (13.72)
		Median	6.0	15.0
		Min, Max	-37, 42	-47, 40
	LS Means (SE)		6.632 (1.8361)	12.232 (1.7310)
	(95% CI)		(2.996, 10.269)	(8.803, 15.660)
	LS Means Difference (SE)			5.600 (2.5235)
	(95% CI)			(0.601, 10.598)
	p-value [2]			0.0779
	Corrected Hedges' G (95% CI)			0.3933 (-0.0466, 0.8332)
	BCVA Score Change from Baseline to 11 Months [1]	n	56	63
		Mean (SD)	6.6 (14.37)	12.3 (13.72)
		Median	6.0	15.0
		Min, Max	-37, 42	-47, 40
	LS Means (SE)		6.632 (1.8361)	12.232 (1.7310)
	(95% CI)		(2.996, 10.269)	(8.803, 15.660)
	LS Means Difference (SE)			5.600 (2.5235)
	(95% CI)			(0.601, 10.598)
	p-value [2]			0.0284
	Corrected Hedges' G (95% CI)			0.4049 (0.0412, 0.7686)

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_87

DATE: 16MAY2024 10:01

Table Morb_88

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter [1]	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	BCVA Score Change from Baseline to 11 Months [2]	n	40	41
		Mean (SD)	4.7 (15.49)	9.6 (9.31)
		Median	6.5	8.0
		Min, Max	-42, 34	-17, 30
	LS Means (SE)		4.683 (2.0070)	9.617 (1.9617)
	(95% CI)		(0.749, 8.617)	(5.772, 13.462)
	LS Means Difference (SE)			4.934 (2.8048)
	(95% CI)			(-0.564, 10.431)
	p-value [3]			0.0786
	Corrected Hedges' G (95% CI)			0.3870 (-0.0527, 0.8267)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_88

DATE: 16MAY2024 5:28

Table Morb_88

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Parameter [1]	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	BCVA Score Change from Baseline to 11 Months [2]	n	56	63
		Mean (SD)	6.6 (14.37)	12.3 (13.72)
		Median	6.0	15.0
		Min, Max	-37, 42	-47, 40
	LS Means (SE)		5.436 (1.8281)	12.265 (1.7630)
	(95% CI)		(1.852, 9.019)	(8.810, 15.721)
	LS Means Difference (SE)			6.829 (2.5416)
	(95% CI)			(1.847, 11.811)
	p-value [3]			0.0072
	Corrected Hedges' G (95% CI)			0.4900 (0.1246, 0.8554)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_88

DATE: 16MAY2024 5:28

Table Morb_89

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Day 30	BCVA Score Change from Baseline	n	44	45
			Mean (SD)	7.7 (9.35)	6.4 (6.83)
			Median	6.0	5.0
			Min, Max	-7, 40	-7, 23
		LS Means (SE) [1] (95% CI)		7.785 (1.5859) (4.642, 10.929)	6.183 (1.5704) (3.070, 9.295)
		LS Means Difference (SE) (95% CI)			-1.603 (2.2319) (-6.026, 2.821)
		p-value			0.4742
		Corrected Hedges' G (95% CI)			-0.1509 (-0.5671, 0.2652)
Male	Day 60	BCVA Score Change from Baseline	n	42	45
			Mean (SD)	6.9 (8.81)	7.1 (7.48)
			Median	6.0	4.0
			Min, Max	-11, 26	-11, 23
		LS Means (SE) [1] (95% CI)		7.778 (1.4650) (4.871, 10.685)	6.947 (1.4440) (4.081, 9.813)
		LS Means Difference (SE) (95% CI)			-0.831 (2.0570) (-4.913, 3.251)
		p-value			0.6870
		Corrected Hedges' G (95% CI)			-0.0859 (-0.5066, 0.3348)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_89

DATE: 16MAY2024 10:48

Table Morb_89

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Day 90	BCVA Score Change from Baseline	n	43	45
			Mean (SD)	9.2 (11.01)	7.9 (7.87)
			Median	10.0	8.0
			Min, Max	-10, 42	-6, 23
		LS Means (SE) [1]		8.951 (1.4900)	7.763 (1.4676)
		(95% CI)		(5.998, 11.905)	(4.854, 10.673)
		LS Means Difference (SE)			-1.188 (2.0914)
		(95% CI)			(-5.334, 2.958)
Male	Day 120		p-value		0.5712
		Corrected Hedges' G (95% CI)			-0.1200 (-0.5384, 0.2983)
		BCVA Score Change from Baseline	n	42	43
			Mean (SD)	8.4 (10.96)	7.0 (8.31)
			Median	8.0	5.0
			Min, Max	-9, 32	-10, 25
		LS Means (SE) [1]		8.579 (1.5388)	7.203 (1.5176)
		(95% CI)		(5.529, 11.628)	(4.195, 10.211)
		LS Means Difference (SE)			-1.375 (2.1612)
		(95% CI)			(-5.658, 2.908)
		p-value			0.5258
		Corrected Hedges' G (95% CI)			-0.1368 (-0.5625, 0.2889)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_89

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Day 150	BCVA Score Change from Baseline	n	40	43
			Mean (SD)	4.9 (12.44)	8.4 (9.30)
			Median	5.5	8.0
			Min, Max	-30, 24	-17, 31
		LS Means (SE) [1]		4.571 (1.7005)	8.194 (1.6714)
		(95% CI)		(1.207, 7.935)	(4.888, 11.501)
		LS Means Difference (SE)			3.624 (2.3844)
		(95% CI)			(-1.093, 8.341)
Male	Day 180	BCVA Score Change from Baseline	n	40	42
			Mean (SD)	8.2 (11.67)	8.1 (10.30)
			Median	9.0	7.0
			Min, Max	-18, 28	-23, 28
		LS Means (SE) [1]		6.764 (1.6912)	8.299 (1.6669)
		(95% CI)		(3.420, 10.109)	(5.002, 11.596)
		LS Means Difference (SE)			1.534 (2.3746)
		(95% CI)			(-3.162, 6.231)
		p-value			0.1310
		Corrected Hedges' G (95% CI)			0.3305 (-0.1030, 0.7641)
		p-value			0.5193
		Corrected Hedges' G (95% CI)			0.1414 (-0.2922, 0.5750)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_89

DATE: 16MAY2024 10:48

Table Morb_89

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Day 210	BCVA Score Change from Baseline	n	42	39
			Mean (SD)	5.7 (12.64)	6.4 (10.48)
			Median	6.0	5.0
			Min, Max	-27, 33	-28, 27
		LS Means (SE) [1]		5.479 (1.6441)	6.950 (1.6394)
		(95% CI)		(2.227, 8.730)	(3.708, 10.192)
		LS Means Difference (SE)			1.472 (2.3218)
		(95% CI)			(-3.120, 6.063)
Male	Day 240	BCVA Score Change from Baseline	n	42	40
			Mean (SD)	3.4 (14.74)	7.8 (10.58)
			Median	3.5	8.0
			Min, Max	-44, 28	-32, 30
		LS Means (SE) [1]		3.204 (1.7515)	8.102 (1.7455)
		(95% CI)		(-0.257, 6.665)	(4.654, 11.551)
		LS Means Difference (SE)			4.898 (2.4728)
		(95% CI)			(0.012, 9.784)
		p-value			0.5273
		Corrected Hedges' G (95% CI)			0.1394 (-0.2970, 0.5758)
		p-value			0.0494
		Corrected Hedges' G (95% CI)			0.4332 (-0.0050, 0.8714)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_89

DATE: 16MAY2024 10:48

Table Morb_89

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-2 Study
 (ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Day 270	BCVA Score Change from Baseline	n	40	39
			Mean (SD)	5.9 (14.43)	9.6 (9.53)
			Median	6.5	9.0
			Min, Max	-43, 31	-16, 28
		LS Means (SE) [1]		5.396 (1.6503)	9.243 (1.6409)
		(95% CI)		(2.134, 8.658)	(6.000, 12.487)
		LS Means Difference (SE)			3.848 (2.3272)
		(95% CI)			(-0.753, 8.448)
Male	Day 300		p-value		0.1005
		Corrected Hedges' G (95% CI)			0.3683 (-0.0765, 0.8132)
		BCVA Score Change from Baseline	n	38	38
			Mean (SD)	5.4 (16.17)	9.2 (9.18)
			Median	8.5	8.0
			Min, Max	-37, 34	-16, 30
		LS Means (SE) [1]		5.268 (1.9605)	8.941 (1.9473)
		(95% CI)		(1.395, 9.141)	(5.094, 12.788)
		LS Means Difference (SE)			3.673 (2.7632)
		(95% CI)			(-1.786, 9.133)
		p-value			0.1857
		Corrected Hedges' G (95% CI)			0.3019 (-0.1504, 0.7541)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.
 [1] LS Means, CI's, and p-values from the repeated measures model.
 Reference Listing: 16.2.6.1

Table Morb_89

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Best Case to MONTH 11	BCVA Score Change from Baseline	n	40	41
			Mean (SD)	4.7 (15.49)	9.6 (9.31)
			Median	6.5	8.0
			Min, Max	-42, 34	-17, 30
		LS Means (SE) [1]		5.083 (1.7461)	9.409 (1.7260)
		(95% CI)		(1.633, 8.533)	(5.998, 12.819)
		LS Means Difference (SE)			4.325 (2.4552)
		(95% CI)			(-0.526, 9.176)
		p-value			0.0801
		Corrected Hedges' G (95% CI)			0.3878 (-0.0520, 0.8275)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_89

DATE: 16MAY2024 10:48

Table Morb_89

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Day 30	BCVA Score Change from Baseline	n	63	66
			Mean (SD)	4.7 (8.39)	6.1 (9.42)
			Median	4.0	4.0
			Min, Max	-22, 28	-27, 32
		LS Means (SE) [1]		4.782 (1.8277)	6.013 (1.8037)
		(95% CI)		(1.177, 8.387)	(2.456, 9.571)
		LS Means Difference (SE)			1.231 (2.5678)
		(95% CI)			(-3.833, 6.296)
Female	Day 60	BCVA Score Change from Baseline	n	63	62
			Mean (SD)	6.3 (11.76)	8.0 (11.83)
			Median	6.0	7.0
			Min, Max	-29, 36	-44, 34
		LS Means (SE) [1]		6.311 (1.6634)	7.833 (1.6545)
		(95% CI)		(3.028, 9.593)	(4.568, 11.098)
		LS Means Difference (SE)			1.522 (2.3461)
		(95% CI)			(-3.108, 6.152)
		p-value			0.6321
		Corrected Hedges' G (95% CI)			0.0839 (-0.2614, 0.4293)
		p-value			0.5173
		Corrected Hedges' G (95% CI)			0.1154 (-0.2356, 0.4663)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_89

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Day 90	BCVA Score Change from Baseline	n	63	62
			Mean (SD)	7.2 (12.16)	10.2 (12.28)
			Median	8.0	10.0
			Min, Max	-26, 36	-46, 32
		LS Means (SE) [1]		6.878 (1.5997)	9.747 (1.5931)
		(95% CI)		(3.718, 10.038)	(6.600, 12.893)
		LS Means Difference (SE)			2.869 (2.2577)
		(95% CI)			(-1.591, 7.328)
Female	Day 120		p-value		0.2058
		Corrected Hedges' G (95% CI)			0.2259 (-0.1259, 0.5776)
		BCVA Score Change from Baseline	n	62	61
			Mean (SD)	8.1 (11.46)	10.6 (12.61)
			Median	7.5	13.0
			Min, Max	-19, 40	-46, 36
		LS Means (SE) [1]		7.057 (1.6432)	10.025 (1.6372)
		(95% CI)		(3.813, 10.301)	(6.793, 13.257)
		LS Means Difference (SE)			2.967 (2.3196)
		(95% CI)			(-1.612, 7.547)
		p-value			0.2026
		Corrected Hedges' G (95% CI)			0.2292 (-0.1254, 0.5839)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_89

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Day 150	BCVA Score Change from Baseline	n	56	63
			Mean (SD)	5.7 (12.36)	10.2 (13.21)
			Median	4.0	12.0
			Min, Max	-27, 34	-46, 34
		LS Means (SE) [1]		4.932 (1.6021)	10.175 (1.5831)
		(95% CI)		(1.768, 8.097)	(7.048, 13.303)
		LS Means Difference (SE)			5.243 (2.2523)
Female	Day 180	(95% CI)			(0.794, 9.692)
		p-value			0.0212
		Corrected Hedges' G (95% CI)			0.4236 (0.0596, 0.7876)
		BCVA Score Change from Baseline	n	55	64
			Mean (SD)	6.1 (14.03)	11.0 (14.01)
			Median	7.0	12.5
			Min, Max	-39, 36	-51, 37
		LS Means (SE) [1]		5.115 (1.6300)	10.784 (1.6026)
		(95% CI)		(1.897, 8.333)	(7.619, 13.948)
		LS Means Difference (SE)			5.669 (2.2859)
		(95% CI)			(1.156, 10.182)
		p-value			0.0141
		Corrected Hedges' G (95% CI)			0.4510 (0.0861, 0.8160)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_89

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Day 210	BCVA Score Change from Baseline	n	53	61
			Mean (SD)	7.2 (13.91)	11.3 (14.74)
			Median	7.0	13.0
			Min, Max	-37, 36	-46, 43
		LS Means (SE) [1]		6.246 (1.7269)	11.541 (1.6888)
		(95% CI)		(2.840, 9.652)	(8.209, 14.872)
		LS Means Difference (SE)			5.295 (2.4154)
		(95% CI)			(0.530, 10.060)
Female	Day 240		p-value		0.0296
		Corrected Hedges' G (95% CI)			0.4075 (0.0356, 0.7794)
		BCVA Score Change from Baseline	n	52	62
			Mean (SD)	6.0 (14.15)	10.8 (14.24)
			Median	6.5	12.0
			Min, Max	-37, 34	-46, 39
		LS Means (SE) [1]		5.453 (1.6257)	10.843 (1.5921)
		(95% CI)		(2.244, 8.663)	(7.699, 13.987)
		LS Means Difference (SE)			5.390 (2.2755)
		(95% CI)			(0.897, 9.882)
		p-value			0.0190
		Corrected Hedges' G (95% CI)			0.4398 (0.0668, 0.8128)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_89

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Day 270	BCVA Score Change from Baseline	n	56	60
			Mean (SD)	7.2 (14.78)	11.4 (13.47)
			Median	8.5	12.5
			Min, Max	-34, 40	-46, 42
		LS Means (SE) [1]		6.476 (1.6394)	11.027 (1.6130)
		(95% CI)		(3.240, 9.712)	(7.843, 14.212)
		LS Means Difference (SE)			4.552 (2.2999)
		(95% CI)			(0.012, 9.092)
Female	Day 300		p-value		0.0494
		Corrected Hedges' G (95% CI)			0.3651 (-0.0022, 0.7323)
		BCVA Score Change from Baseline	n	54	63
			Mean (SD)	7.4 (14.64)	11.3 (13.29)
			Median	7.5	14.0
			Min, Max	-34, 41	-46, 41
		LS Means (SE) [1]		7.059 (1.6918)	11.266 (1.6526)
		(95% CI)		(3.721, 10.397)	(8.005, 14.528)
		LS Means Difference (SE)			4.207 (2.3650)
		(95% CI)			(-0.460, 8.874)
		p-value			0.0770
		Corrected Hedges' G (95% CI)			0.3264 (-0.0396, 0.6923)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_89

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-2 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Female	Best Case to MONTH 11	BCVA Score Change from Baseline	n	56	63
			Mean (SD)	6.6 (14.37)	12.3 (13.72)
			Median	6.0	15.0
			Min, Max	-37, 42	-47, 40
		LS Means (SE) [1]		5.751 (1.6787)	12.218 (1.6429)
		(95% CI)		(2.439, 9.064)	(8.975, 15.461)
		LS Means Difference (SE)			6.467 (2.3489)
		(95% CI)			(1.831, 11.102)
		p-value			0.0065
		Corrected Hedges' G (95% CI)			0.5013 (0.1356, 0.8669)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a working autoregressive with heterogeneity (ARH(1)) correlation structure, which was determined based on modeling several correlation structures and comparing Akaike Information Criterion (AIC). The working correlation structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_89

DATE: 16MAY2024 10:48

Table Morb_90

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Gender in NORSE-2 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Male	Number of Subjects, n/N1 (%) [1]	11/ 42 (26.2)	6/ 43 (14.0)
	Odds Ratio [2]	0.4570	
	95% CI	(0.1516, 1.3774)	
	Relative Risk [2]	0.5328	
	95% CI	(0.2168, 1.3094)	
	Absolute Risk Reduction [2]	-0.1224	
	95% CI	(-0.3000, 0.0527)	
	p-value [3]	0.1842	
Female	Number of Subjects, n/N1 (%) [1]	14/ 62 (22.6)	8/ 65 (12.3)
	Odds Ratio [2]	0.4812	
	95% CI	(0.1862, 1.2439)	
	Relative Risk [2]	0.5451	
	95% CI	(0.2459, 1.2081)	
	Absolute Risk Reduction [2]	-0.1027	
	95% CI	(-0.2409, 0.0336)	
	p-value [3]	0.1609	
Interaction	p-value [4]	0.8084	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment. Percentages based on N1.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_91

Subjects Gaining >=15 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Yes	Number of Subjects, n/N1 (%) [1]	1/ 5 (20.0)	1/ 4 (25.0)
	Odds Ratio [2]	1.3333	
	95% CI	(0.0571, 31.1210)	
	Relative Risk [2]	1.2500	
	95% CI	(0.1089, 14.3432)	
	Absolute Risk Reduction [2]	0.0500	
	95% CI	(-0.5831, 0.6545)	
No	p-value [3]	1.0000	
	Number of Subjects, n/N1 (%) [1]	23/ 99 (23.2)	44/104 (42.3)
	Odds Ratio [2]	2.4232	
	95% CI	(1.3201, 4.4480)	
	Relative Risk [2]	1.8211	
	95% CI	(1.1934, 2.7788)	
	Absolute Risk Reduction [2]	0.1908	
Interaction	95% CI	(0.0458, 0.3169)	
	p-value [3]	0.0046	
		0.0057	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment. Percentages based on N1.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_92

Subjects Gaining >=10 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Yes	Number of Subjects, n/N1 (%) [1]	1/ 5 (20.0)	3/ 4 (75.0)
	Odds Ratio [2]	12.0000	
	95% CI	(0.5141, 280.0892)	
	Relative Risk [2]	3.7500	
	95% CI	(0.5943, 23.6614)	
	Absolute Risk Reduction [2]	0.5500	
	95% CI	(-0.2086, 0.9371)	
No	p-value [3]	0.2063	
	Number of Subjects, n/N1 (%) [1]	35/ 99 (35.4)	58/104 (55.8)
	Odds Ratio [2]	2.3056	
	95% CI	(1.3101, 4.0576)	
	Relative Risk [2]	1.5775	
	95% CI	(1.1494, 2.1651)	
	Absolute Risk Reduction [2]	0.2042	
Interaction	95% CI	(0.0486, 0.3372)	
	p-value [3]	0.0047	
	p-value [4]	0.0123	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment. Percentages based on N1.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_93

Subjects Gaining >=5 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Yes	Number of Subjects, n/N1 (%) [1]	2/ 5 (40.0)	3/ 4 (75.0)
	Odds Ratio [2]	4.5000	
	95% CI	(0.2513, 80.5652)	
	Relative Risk [2]	1.8750	
	95% CI	(0.5572, 6.3098)	
	Absolute Risk Reduction [2]	0.3500	
	95% CI	(-0.3596, 0.8439)	
No	p-value [3]	0.5238	
	Number of Subjects, n/N1 (%) [1]	51/ 99 (51.5)	71/104 (68.3)
	Odds Ratio [2]	2.0250	
	95% CI	(1.1442, 3.5837)	
	Relative Risk [2]	1.3252	
	95% CI	(1.0511, 1.6708)	
	Absolute Risk Reduction [2]	0.1675	
Interaction	95% CI	(0.0255, 0.3020)	
	p-value [3]	0.0215	
		0.0315	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment. Percentages based on N1.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_94

Subjects Loosing < 15 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Yes	Number of Subjects, n/N1 (%) [1]	4/ 5 (80.0)	4/ 4 (100.0)
	Odds Ratio [2]	-	-
	95% CI	-	-
	Relative Risk [2]	1.2500	
	95% CI	(0.8064, 1.9375)	
	Absolute Risk Reduction [2]	0.2000	
	95% CI	(-0.4185, 0.7164)	
No	p-value [3]	1.0000	
	Number of Subjects, n/N1 (%) [1]	82/ 99 (82.8)	97/104 (93.3)
	Odds Ratio [2]	2.8728	
	95% CI	(1.1357, 7.2667)	
	Relative Risk [2]	1.1261	
	95% CI	(1.0153, 1.2488)	
	Absolute Risk Reduction [2]	0.1044	
Interaction	95% CI	(0.0144, 0.2009)	
	p-value [3]	0.0287	
	p-value [4]	0.0436	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment. Percentages based on N1.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_95

BCVA Change from Baseline - Trimmed Means Fixed Approach by Prior Anti-VEGF Therapy in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Yes	BCVA Score Change from Baseline to 11 Months [1]	n	4	4
No	BCVA Score Change from Baseline to 11 Months [1]	n	92	100

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_95

DATE: 30APR2024 15:22

Table Morb_96

BCVA Change from Baseline - Trimmed Means Adaptive Approach by Prior Anti-VEGF Therapy in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Yes	BCVA Score Change from Baseline to 11 Months [1]	n	4	4
No	BCVA Score Change from Baseline to 11 Months [1]	n	92	100

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_96

DATE: 30APR2024 15:25

Table Morb_97

BCVA Change from Baseline - Analysis of Covariance by Prior Anti-VEGF Therapy in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Yes	BCVA Score Change from Baseline to 11 Months [1]	n	4	4
No	BCVA Score Change from Baseline to 11 Months [1]	n	92	100

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_97

DATE: 30APR2024 15:30

Table Morb_98

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Prior Anti-VEGF Therapy in NORSE-2 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Yes	BCVA Score Change from Baseline to 11 Months [1]	n	4	4
No	BCVA Score Change from Baseline to 11 Months [1]	n	92	100

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_98

DATE: 30APR2024 15:34

Table Morb_99

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-2 Study
(ITT Population)

Visit	Subgroup	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Day 30	Yes	BCVA Score Change from Baseline	n	4	4
	No	BCVA Score Change from Baseline	n	103	107
Day 60	Yes	BCVA Score Change from Baseline	n	5	3
	No	BCVA Score Change from Baseline	n	100	104
Day 90	Yes	BCVA Score Change from Baseline	n	5	4
	No	BCVA Score Change from Baseline	n	101	103
Day 120	Yes	BCVA Score Change from Baseline	n	5	3
	No	BCVA Score Change from Baseline	n	99	101
Day 150	Yes	BCVA Score Change from Baseline	n	5	4
	No	BCVA Score Change from Baseline	n	91	102
Day 180	Yes	BCVA Score Change from Baseline	n	3	4
	No	BCVA Score Change from Baseline	n	92	102

Note: BCVA = Best Corrected Visual Acuity.
Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients
Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_99

DATE: 30APR2024 15:37

Table Morb_99

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-2 Study
(ITT Population)

Visit	Subgroup	Parameter	Statistic	Ranibizumab (N=115)	ONS-5010 (N=113)
Day 210	Yes	BCVA Score Change from Baseline	n	4	2
	No	BCVA Score Change from Baseline	n	91	98
Day 240	Yes	BCVA Score Change from Baseline	n	2	4
	No	BCVA Score Change from Baseline	n	92	98
Day 270	Yes	BCVA Score Change from Baseline	n	4	3
	No	BCVA Score Change from Baseline	n	92	96
Day 300	Yes	BCVA Score Change from Baseline	n	2	4
	No	BCVA Score Change from Baseline	n	90	97
Best Case to MONTH 11	Yes	BCVA Score Change from Baseline	n	4	4
	No	BCVA Score Change from Baseline	n	92	100

Note: BCVA = Best Corrected Visual Acuity.

Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_99

DATE: 30APR2024 15:37

Table Morb_100

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Prior Anti-VEGF Therapy in NORSE-2 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Yes	Number of Subjects, n/N1 (%) [1]	1/ 5 (20.0)	0/ 4
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	NE (NE, NE)	
	Absolute Risk Reduction [2] 95% CI	-0.1500 (-, -)*	
	p-value [3]	NE	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.
20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_100

DATE: 19JUN2024 9:14

Table Morb_100

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Prior Anti-VEGF Therapy in NORSE-2 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
No	Number of Subjects, n/N1 (%) [1]	24/ 99 (24.2)	14/104 (13.5)
	Odds Ratio [2] 95% CI	0.4861 (0.2169,1.0619)	
	Relative Risk [2] 95% CI	0.5553 (0.2878,1.0106)	
	Absolute Risk Reduction [2] 95% CI	-0.1078 (-0.2184,0.0016)	
	p-value [3]	0.0710	
Interaction	p-value [4]	0.0760	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_100

DATE: 19JUN2024 9:14

Table Morb_100

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Prior Anti-VEGF Therapy in NORSE-2 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
Yes	Number of Subjects, n/N (%) [1]	1/ 5 (20.0)	0/ 4
	Odds Ratio [2] 95% CI	0.3333 (-, -)*	
	Relative Risk [2] 95% CI	NE (NE, NE)	
	Absolute Risk Reduction [2] 95% CI	-0.1500 (-, -)*	
	p-value [3]	NE	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.
20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_100

DATE: 19JUN2024 9:14

Table Morb_100

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Prior Anti-VEGF Therapy in NORSE-2 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=115)	ONS-5010 (N=113)
No	Number of Subjects, n/N (%) [1]	24/110 (21.8)	14/109 (12.8)
	Odds Ratio [2] 95% CI	0.5281 (0.2370, 1.1448)	
	Relative Risk [2] 95% CI	0.5887 (0.3029, 1.0784)	
	Absolute Risk Reduction [2] 95% CI	-0.0897 (-0.1946, 0.0137)	
	p-value [3]	0.1076	
Interaction	p-value [4]	0.1163	

Note: Those patients who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_100

DATE: 19JUN2024 9:14

Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years							
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
At Least 1 TEAE	n (%)	40 (74.1)	41 (66.1)	0.6833 (0.3057, 1.5275)	0.8927 (0.7037, 1.1326)	-0.0795 (-0.2454, 0.0865) 0.3545	
Eye disorders	n (%)	30 (55.6)	27 (43.5)	0.6171 (0.2959, 1.2870)	0.7839 (0.5412, 1.1353)	-0.1201 (-0.3012, 0.0610) 0.1989	
Neovascular age-related macular degeneration	n (%)	8 (14.8)	4 (6.5)	0.3966 (0.1124, 1.3995)	0.4355 (0.1388, 1.3663)	-0.0836 (-0.1964, 0.0291) 0.1418	
Conjunctival haemorrhage	n (%)	2 (3.7)	7 (11.3)	-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_74

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Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Visual acuity reduced	n (%)	7 (13.0)	2 (3.2)	0.2238 (0.0444, 1.1277)	0.2488 (0.0540, 1.1475)	-0.0974 (-0.1972, 0.0024)	0.0515
Subretinal fluid	n (%)	5 (9.3)	2 (3.2)	-	-	-	-
Retinal haemorrhage	n (%)	3 (5.6)	3 (4.8)	-	-	-	-
Corneal abrasion	n (%)	1 (1.9)	3 (4.8)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Punctate keratitis	n (%)	1 (1.9)	3 (4.8)	-	-	-	-
				-	-	-	-
Vision blurred	n (%)	1 (1.9)	2 (3.2)	-	-	-	-
				-	-	-	-
Vitreous floaters	n (%)	1 (1.9)	2 (3.2)	-	-	-	-
				-	-	-	-
Dermatochalasis	n (%)	2 (3.7)	1 (1.6)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Dry eye	n (%)	2 (3.7)	1 (1.6)	-	-	-	-
				-	-	-	-
Eye pain	n (%)	2 (3.7)	1 (1.6)	-	-	-	-
				-	-	-	-
Metamorphopsia	n (%)	2 (3.7)	1 (1.6)	-	-	-	-
				-	-	-	-
Subretinal fibrosis	n (%)	2 (3.7)	1 (1.6)	-	-	-	-
				-	-	-	-

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Eye disorders							
Retinal oedema		n (%)	3 (5.6)	0	-	-	-
					-	-	-
Eye irritation		n (%)	0	2 (3.2)	-	-	-
					-	-	-
Vitreous detachment		n (%)	0	2 (3.2)	-	-	-
					-	-	-
Cataract		n (%)	1 (1.9)	1 (1.6)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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< 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Cataract cortical		n (%)	1 (1.9)	1 (1.6)	-	-	-
					-	-	-
Conjunctival hyperaemia		n (%)	2 (3.7)	0	-	-	-
					-	-	-
Detachment of retinal pigment epithelium		n (%)	2 (3.7)	0	-	-	-
					-	-	-
Dry age-related macular degeneration		n (%)	2 (3.7)	0	-	-	-
					-	-	-

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Eye disorders							
Cataract nuclear		n (%)	0	1 (1.6)	-	-	-
					-	-	-
Chorioretinopathy		n (%)	0	1 (1.6)	-	-	-
					-	-	-
Conjunctivitis allergic		n (%)	0	1 (1.6)	-	-	-
					-	-	-
Iritis		n (%)	0	1 (1.6)	-	-	-
					-	-	-

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< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Macular hole	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Photopsia	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Retinal pigment epithelial tear	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Retinal tear	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-

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MedDRA Preferred Term							
Eye disorders							
Trichiasis	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Vitreous opacities	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Blepharitis	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-
Blindness	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-

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Eye disorders							
Lacrimation increased		n (%)	1 (1.9)	0	-	-	-
					-	-	-
Macular oedema		n (%)	1 (1.9)	0	-	-	-
					-	-	-
Macular pigmentation		n (%)	1 (1.9)	0	-	-	-
					-	-	-
Retinal drusen		n (%)	1 (1.9)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Eye disorders							
Vitreous haemorrhage		n (%)	1 (1.9)	0	-	-	-
					-	-	-
Investigations		n (%)	6 (11.1)	11 (17.7)	1.7255 (0.5919, 5.0303)	1.5968 (0.6329, 4.0285)	0.0663 (-0.0605, 0.1931)
Intraocular pressure increased		n (%)	0	4 (6.5)	-	-	-
					-	-	-
Blood pressure increased		n (%)	1 (1.9)	2 (3.2)	-	-	-
					-	-	-

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< 80 years							Absolute Risk Difference
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Investigations							
Blood pressure diastolic decreased	n (%)	0	2 (3.2)	-	-	-	-
Urine analysis abnormal	n (%)	2 (3.7)	0	-	-	-	-
Bacterial test positive	n (%)	0	1 (1.6)	-	-	-	-
Blood creatinine increased	n (%)	0	1 (1.6)	-	-	-	-

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Investigations							
Blood pressure diastolic increased	n (%)	0	1 (1.6)	- -	- -	- -	- -
Blood triglycerides increased	n (%)	0	1 (1.6)	- -	- -	- -	- -
Haematocrit decreased	n (%)	0	1 (1.6)	- -	- -	- -	- -
Haemoglobin decreased	n (%)	0	1 (1.6)	- -	- -	- -	- -

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Investigations							
Laboratory test abnormal	n (%)	0	1 (1.6)	-	-		-
				-	-		-
Lymphocyte count decreased	n (%)	0	1 (1.6)	-	-		-
				-	-		-
Monocyte count increased	n (%)	0	1 (1.6)	-	-		-
				-	-		-
Neutrophil count increased	n (%)	0	1 (1.6)	-	-		-
				-	-		-

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< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Urine leukocyte esterase positive	n (%)	0	1 (1.6)	-	-	-	-
Weight decreased	n (%)	0	1 (1.6)	-	-	-	-
White blood cell count increased	n (%)	0	1 (1.6)	-	-	-	-
Blood creatinine abnormal	n (%)	1 (1.9)	0	-	-	-	-

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(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood urea abnormal	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-
Blood uric acid increased	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-
White blood cells urine positive	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	5 (9.3)	9 (14.5)	1.6642 (0.5216, 5.3094)	1.5677 (0.5594, 4.3937)	0.0526 (-0.0643, 0.1695)	0.3880

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_74

DATE: 16JUL2024 11:01

Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Infections and infestations							
Urinary tract infection	n (%)	3 (5.6)	5 (8.1)	-	-	-	-
				-	-	-	-
Sinusitis	n (%)	1 (1.9)	2 (3.2)	-	-	-	-
				-	-	-	-
Bronchitis	n (%)	1 (1.9)	1 (1.6)	-	-	-	-
				-	-	-	-
COVID-19	n (%)	2 (3.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Infections and infestations							
Clostridium difficile infection	n (%)	0	1 (1.6)	-	-	-	-
Conjunctivitis	n (%)	0	1 (1.6)	-	-	-	-
Pneumonia	n (%)	0	1 (1.6)	-	-	-	-
Upper respiratory tract infection	n (%)	0	1 (1.6)	-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years							
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	
MedDRA Preferred Term	Statistic	Ranibizumab (N=54)	(Masked Data)[1] (N=62)			p-value[2]	
Injury, poisoning and procedural complications	n (%)	4 (7.4)	6 (9.7)	1.3393 (0.3573, 5.0204)	1.3065 (0.3890, 4.3873)	0.0227 (-0.0788, 0.1242) 0.6653	
Fall	n (%)	2 (3.7)	1 (1.6)	-	-	-	
Procedural pain	n (%)	1 (1.9)	1 (1.6)	-	-	-	
Contusion	n (%)	0	1 (1.6)	-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications							
Face injury	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Facial bones fracture	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Head injury	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Skin abrasion	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-

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(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications						
Tooth fracture	n (%)	0	1 (1.6)	-	-	-
				-	-	-
Rib fracture	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Nervous system disorders	n (%)	4 (7.4)	3 (4.8)	-	-	-
				-	-	-
Headache	n (%)	2 (3.7)	1 (1.6)	-	-	-
				-	-	-

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< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Dizziness	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Parkinson's disease	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Cerebral infarction	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-
Dementia	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-

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< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	p-value[2]	95% CI
Metabolism and nutrition disorders	n (%)	3 (5.6)	3 (4.8)	-	-	-	-
Hyperlipidaemia	n (%)	1 (1.9)	2 (3.2)	-	-	-	-
Vitamin D deficiency	n (%)	0	1 (1.6)	-	-	-	-
Diabetes mellitus	n (%)	1 (1.9)	0	-	-	-	-

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MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Metabolism and nutrition disorders							
Glucose tolerance impaired	n (%)	1 (1.9)	0	-	-		-
							-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	3 (5.6)	3 (4.8)	-	-		-
							-
Squamous cell carcinoma of skin	n (%)	0	2 (3.2)	-	-		-
							-
Squamous cell carcinoma of the oral cavity	n (%)	0	1 (1.6)	-	-		-
							-

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MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acrochordon		n (%)	1 (1.9)	0	-	-	-
					-	-	-
Bladder cancer recurrent		n (%)	1 (1.9)	0	-	-	-
					-	-	-
Squamous cell carcinoma of the tongue		n (%)	1 (1.9)	0	-	-	-
					-	-	-
Vascular disorders		n (%)	4 (7.4)	2 (3.2)	0.4167 (0.0733, 2.3700)	0.4355 (0.0830, 2.2851)	-0.0418 (-0.1244, 0.0407) 0.3125

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MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Vascular disorders							
Essential hypertension		n (%)	1 (1.9)	1 (1.6)	-	-	-
					-	-	-
Hypertension		n (%)	0	1 (1.6)	-	-	-
					-	-	-
Hot flush		n (%)	1 (1.9)	0	-	-	-
					-	-	-
Hypotension		n (%)	1 (1.9)	0	-	-	-
					-	-	-

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MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Vascular disorders							
Venous occlusion	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-
Respiratory, thoracic and mediastinal disorders	n (%)	3 (5.6)	1 (1.6)	-	-	-	-
				-	-	-	-
Chronic obstructive pulmonary disease	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Cough	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-

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< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Epistaxis	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Asthma	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-
Nasal congestion	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-
Oropharyngeal pain	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-

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< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pleural effusion	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-
Cardiac disorders	n (%)	0	3 (4.8)	NE (NE, NE)	NE (NE, NE)	0.0484 (-0.0050, 0.1018)	0.1030
Acute myocardial infarction	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-
Coronary artery disease	n (%)	0	1 (1.6)	-	-	-	-
				-	-	-	-

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< 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Cardiac disorders							
Myocardial infarction		n (%)	0	1 (1.6)	-	-	-
					-	-	-
Musculoskeletal and connective tissue disorders							
Back pain		n (%)	0	3 (4.8)	-	-	-
					-	-	-
Ligament sprain		n (%)	0	1 (1.6)	-	-	-
					-	-	-

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< 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
	Plantar fasciitis	n (%)	0	1 (1.6)	-	-	-
					-	-	-
Immune system disorders		n (%)	1 (1.9)	2 (3.2)	-	-	-
					-	-	-
	Allergy to arthropod bite	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Iodine allergy	n (%)	0	1 (1.6)	-	-	-
					-	-	-

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(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Immune system disorders							
Allergic sinusitis		n (%)	1 (1.9)	0	-	-	-
					-	-	-
Psychiatric disorders							
Anxiety		n (%)	0	1 (1.6)	-	-	-
					-	-	-
Stress		n (%)	1 (1.9)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_74

DATE: 16JUL2024 11:01

Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Renal and urinary disorders	n (%)	2 (3.7)	0	-	-	-
Haematuria	n (%)	1 (1.9)	0	-	-	-
Nephrolithiasis	n (%)	1 (1.9)	0	-	-	-
Reproductive system and breast disorders	n (%)	0	1 (1.6)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study (Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Reproductive system and breast disorders							
Prostatomegaly		n (%)	0	1 (1.6)	-	-	-
					-	-	-
Skin and subcutaneous tissue disorders		n (%)	0	1 (1.6)	-	-	-
					-	-	-
Tinea cruris		n (%)	0	1 (1.6)	-	-	-
					-	-	-
Blood and lymphatic system disorders		n (%)	1 (1.9)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Blood and lymphatic system disorders							
Lymphadenopathy	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-
Gastrointestinal disorders	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-
Nausea	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-

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Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years							
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
At Least 1 TEAE	n (%)	45 (73.8)	41 (80.4)	1.4578 (0.5949, 3.5722)	1.0898 (0.8905, 1.3336)	0.0662 (-0.0889, 0.2213) 0.4106	
Eye disorders	n (%)	30 (49.2)	23 (45.1)	0.8488 (0.4026, 1.7894)	0.9170 (0.6172, 1.3625)	-0.0408 (-0.2263, 0.1446) 0.6679	
Visual acuity reduced	n (%)	10 (16.4)	1 (2.0)	0.1020 (0.0126, 0.8266)	0.1196 (0.0158, 0.9032)	-0.1443 (-0.2447, -0.0439) 0.0109	
Neovascular age-related macular degeneration	n (%)	4 (6.6)	5 (9.8)	1.5489 (0.3932, 6.1014)	1.4951 (0.4236, 5.2766)	0.0325 (-0.0701, 0.1350) 0.5309	

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Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Dry eye		n (%)	3 (4.9)	2 (3.9)	-	-	-
					-	-	-
Retinal haemorrhage		n (%)	5 (8.2)	0	-	-	-
					-	-	-
Conjunctival haemorrhage		n (%)	1 (1.6)	3 (5.9)	-	-	-
					-	-	-
Posterior capsule opacification		n (%)	3 (4.9)	1 (2.0)	-	-	-
					-	-	-

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(Safety Population)

>= 80 years							Absolute Risk Difference
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MedDRA Preferred Term							
Eye disorders							
Vitreous floaters	n (%)	0	3 (5.9)	-	-	-	-
				-	-	-	-
Cystoid macular oedema	n (%)	2 (3.3)	1 (2.0)	-	-	-	-
				-	-	-	-
Hordeolum	n (%)	2 (3.3)	1 (2.0)	-	-	-	-
				-	-	-	-
Retinal degeneration	n (%)	2 (3.3)	1 (2.0)	-	-	-	-
				-	-	-	-

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>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Vitreous detachment	n (%)		2 (3.3)	1 (2.0)	-	-	-
					-	-	-
Cataract nuclear	n (%)	0	0	2 (3.9)	-	-	-
					-	-	-
Corneal abrasion	n (%)	0	0	2 (3.9)	-	-	-
					-	-	-
Eye pain	n (%)	0	0	2 (3.9)	-	-	-
					-	-	-

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>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Subretinal fluid		n (%)	0	2 (3.9)	-	-	-
					-	-	-
Vitreous haemorrhage		n (%)	0	2 (3.9)	-	-	-
					-	-	-
Cataract		n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
Macular scar		n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-

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(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Retinal pigmentation	n (%)	1 (1.6)	1 (2.0)	-	-	-	-
							-
Metamorphopsia	n (%)	2 (3.3)	0	-	-	-	-
							-
Retinal vein occlusion	n (%)	2 (3.3)	0	-	-	-	-
							-
Angle closure glaucoma	n (%)	0	1 (2.0)	-	-	-	-
							-

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>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value[2]
MedDRA Preferred Term							
Eye disorders							
Choroidal neovascularisation	n (%)	0	1 (2.0)	- -	- -	- -	- -
Dacryostenosis acquired	n (%)	0	1 (2.0)	- -	- -	- -	- -
Dermatochalasis	n (%)	0	1 (2.0)	- -	- -	- -	- -
Eye swelling	n (%)	0	1 (2.0)	- -	- -	- -	- -

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>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Iridocyclitis		n (%)	0	1 (2.0)	-	-	-
					-	-	-
Photopsia		n (%)	0	1 (2.0)	-	-	-
					-	-	-
Subretinal fibrosis		n (%)	0	1 (2.0)	-	-	-
					-	-	-
Dry age-related macular degeneration		n (%)	1 (1.6)	0	-	-	-
					-	-	-

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(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Entropion	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Exposure keratitis	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Eyelid ptosis	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Foveal degeneration	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-

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>= 80 years							Absolute Risk Difference
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Eye disorders							
Lacrimation increased		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Macular fibrosis		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Meibomian gland dysfunction		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Punctate keratitis		n (%)	1 (1.6)	0	-	-	-
					-	-	-

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>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Retinal detachment		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Retinal oedema		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Retinal tear		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Vision blurred		n (%)	1 (1.6)	0	-	-	-
					-	-	-

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(Safety Population)

>= 80 years							
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference	
MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	(Masked Data)[1] (N=51)			95% CI	p-value[2]
Infections and infestations	n (%)	9 (14.8)	9 (17.6)	1.2381 (0.4512, 3.3975)	1.1961 (0.5134, 2.7866)	0.0289 (-0.1084, 0.1663)	0.6794
COVID-19	n (%)	2 (3.3)	3 (5.9)	-	-	-	-
Urinary tract infection	n (%)	2 (3.3)	3 (5.9)	-	-	-	-
Acute sinusitis	n (%)	0	1 (2.0)	-	-	-	-

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_74

DATE: 16JUL2024 11:01

Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value[2]
MedDRA Preferred Term							
Infections and infestations							
Fungal infection	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Influenza	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Anogenital warts	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Bronchitis	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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(Safety Population)

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MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Infections and infestations							
COVID-19 pneumonia	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Cellulitis	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Herpes zoster	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Pneumonia	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-

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(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Infections and infestations							
Pyelonephritis	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Sepsis	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Investigations	n (%)	7 (11.5)	7 (13.7)	1.2273 (0.4001, 3.7641)	1.1961 (0.4492, 3.1850)	0.0225 (-0.1013, 0.1463)	0.7211
Intraocular pressure increased	n (%)	1 (1.6)	3 (5.9)	-	-	-	-
				-	-	-	-

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>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Investigations							
Urine analysis abnormal		n (%)	0	2 (3.9)	-	-	-
					-	-	-
Blood pressure increased		n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
Bacterial test positive		n (%)	0	1 (2.0)	-	-	-
					-	-	-
Blood pressure diastolic decreased		n (%)	0	1 (2.0)	-	-	-
					-	-	-

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>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Investigations							
Protein urine present	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Basophil count increased	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Eosinophil count increased	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Haematocrit decreased	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-

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>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Haemoglobin decreased	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Neutrophil count increased	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Platelet count decreased	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Red blood cell count decreased	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-

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Investigations							
Red blood cells urine positive		n (%)	1 (1.6)	0	-	-	-
					-	-	-
White blood cell count increased		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Vascular disorders		n (%)	7 (11.5)	4 (7.8)	0.6565 (0.1809, 2.3831)	0.6835 (0.2120, 2.2040)	-0.0363 (-0.1451, 0.0725) 0.5219
Syncope		n (%)	2 (3.3)	1 (2.0)	-	-	-
					-	-	-

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(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Vascular disorders							
Hypotension	n (%)	1 (1.6)	1 (2.0)	-	-	-	-
				-	-	-	-
Dizziness	n (%)	2 (3.3)	0	-	-	-	-
				-	-	-	-
Essential hypertension	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Transient ischaemic attack	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-

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>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Vascular disorders							
Aortic arteriosclerosis		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Epistaxis		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Hypertension		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Pulmonary congestion		n (%)	1 (1.6)	0	-	-	-
					-	-	-

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(Safety Population)

>= 80 years							
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	
MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	(Masked Data)[1] (N=51)			p-value[2]	
Cardiac disorders	n (%)	5 (8.2)	5 (9.8)	1.2174 (0.3319, 4.4647)	1.1961 (0.3666, 3.9022)	0.0161 (-0.0907, 0.1228)	0.7674
Atrial fibrillation	n (%)	2 (3.3)	2 (3.9)	-	-	-	-
Cardiac failure congestive	n (%)	2 (3.3)	0	-	-	-	-
Pericardial effusion	n (%)	2 (3.3)	0	-	-	-	-

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MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) [1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value [2]
Cardiac disorders							
Aortic valve stenosis		n (%)	0	1 (2.0)	-	-	-
					-	-	-
Arrhythmia		n (%)	0	1 (2.0)	-	-	-
					-	-	-
Bradycardia		n (%)	0	1 (2.0)	-	-	-
					-	-	-
Bundle branch block		n (%)	0	1 (2.0)	-	-	-
					-	-	-

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Cardiac disorders							
	Bundle branch block right	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Cardiac arrest	n (%)	1 (1.6)	0	-	-	-
					-	-	-
Injury, poisoning and procedural complications		n (%)	5 (8.2)	5 (9.8)	1.2174 (0.3319, 4.4647)	1.1961 (0.3666, 3.9022)	0.0161 (-0.0907, 0.1228)
	Fall	n (%)	2 (3.3)	2 (3.9)	-	-	0.7674
					-	-	-

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Injury, poisoning and procedural complications							
Head injury	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Rib fracture	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Skin laceration	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Hip fracture	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-

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Injury, poisoning and procedural complications							
Joint injury	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Procedural pain	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Traumatic haematoma	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Renal and urinary disorders	n (%)	4 (6.6)	5 (9.8)	-	-	-	-
				-	-	-	-

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MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders							
Haematuria	n (%)	2 (3.3)	1 (2.0)	-	-	-	-
				-	-	-	-
Cystitis	n (%)	0	2 (3.9)	-	-	-	-
				-	-	-	-
Dysuria	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Urinary tract infection	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-

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Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders							
Acute kidney injury	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Bladder diverticulum	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Haemorrhage urinary tract	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Renal cyst	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Renal and urinary disorders							
	Renal tubular necrosis	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Urinary bladder haemorrhage	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Urinary retention	n (%)	1 (1.6)	0	-	-	-
					-	-	-
Metabolism and nutrition disorders							
		n (%)	5 (8.2)	3 (5.9)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Metabolism and nutrition disorders							
Vitamin D deficiency	n (%)	1 (1.6)	1 (2.0)	-	-	-	-
				-	-	-	-
Dyslipidaemia	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Hyponatraemia	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Dehydration	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-

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Metabolism and nutrition disorders							
Hyperkalaemia		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Hypokalaemia		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Hypomagnesaemia		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Malnutrition		n (%)	1 (1.6)	0	-	-	-
					-	-	-

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>= 80 years						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	(Masked Data)[1] (N=51)			
Nervous system disorders	n (%)	6 (9.8)	1 (2.0)	-	-	-
				-	-	-
Migraine	n (%)	0	1 (2.0)	-	-	-
				-	-	-
Cerebral small vessel ischaemic disease	n (%)	1 (1.6)	0	-	-	-
				-	-	-
Cerebrovascular accident	n (%)	1 (1.6)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Confusional state	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Embollic stroke	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Facial paralysis	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Metabolic encephalopathy	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-

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Nervous system disorders							
Sciatica	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Seizure	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Tremor	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	3 (4.9)	3 (5.9)	-	-	-	-
				-	-	-	-

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Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acute leukaemia		n (%)	0	1 (2.0)	-	-	-
Basal cell carcinoma		n (%)	0	1 (2.0)	-	-	-
Keratoacanthoma		n (%)	0	1 (2.0)	-	-	-
Bladder cancer		n (%)	1 (1.6)	0	-	-	-

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Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder neoplasm		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Eye naevus		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Skin cancer		n (%)	1 (1.6)	0	-	-	-
					-	-	-
General disorders and administration site conditions		n (%)	4 (6.6)	2 (3.9)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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General disorders and administration site conditions							
Asthenia	n (%)	0	1 (2.0)	-	-		-
				-	-		-
Death	n (%)	0	1 (2.0)	-	-		-
				-	-		-
Cardiac death	n (%)	1 (1.6)	0	-	-		-
				-	-		-
Gait inability	n (%)	1 (1.6)	0	-	-		-
				-	-		-

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MedDRA Preferred Term							
General disorders and administration site conditions							
Peripheral swelling	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Pyrexia	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Skin and subcutaneous tissue disorders	n (%)	2 (3.3)	3 (5.9)	-	-	-	-
				-	-	-	-
Skin lesion	n (%)	1 (1.6)	1 (2.0)	-	-	-	-
				-	-	-	-

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Skin and subcutaneous tissue disorders							
Ecchymosis	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Eczema	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Rash	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Musculoskeletal and connective tissue disorders	n (%)	3 (4.9)	2 (3.9)	-	-	-	-
				-	-	-	-

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Musculoskeletal and connective tissue disorders							
Back pain		n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
Bursitis		n (%)	0	1 (2.0)	-	-	-
					-	-	-
Hand fracture		n (%)	1 (1.6)	0	-	-	-
					-	-	-
Joint swelling		n (%)	1 (1.6)	0	-	-	-
					-	-	-

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Musculoskeletal and connective tissue disorders							
Pain in extremity	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Respiratory, thoracic and mediastinal disorders	n (%)	4 (6.6)	1 (2.0)	-	-	-	-
				-	-	-	-
Respiratory failure	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Atelectasis	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-

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Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease	n (%)	1 (1.6)	0	-	-	-	-
Cough	n (%)	1 (1.6)	0	-	-	-	-
Hypoxia	n (%)	1 (1.6)	0	-	-	-	-
Pleural effusion	n (%)	1 (1.6)	0	-	-	-	-

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Respiratory, thoracic and mediastinal disorders							
Pneumonia	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Pulmonary fibrosis	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Pulmonary oedema	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Blood and lymphatic system disorders	n (%)	1 (1.6)	2 (3.9)	-	-	-	-
				-	-	-	-

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_74

DATE: 16JUL2024 11:01

Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Blood and lymphatic system disorders							
Anaemia	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Microcytic anaemia	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Blood loss anaemia	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Gastrointestinal disorders	n (%)	2 (3.3)	1 (2.0)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_74

DATE: 16JUL2024 11:01

Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Gastrointestinal disorders							
Small intestinal obstruction	n (%)	0	1 (2.0)	-	-		-
				-	-		-
Gastrooesophageal reflux disease	n (%)	1 (1.6)	0	-	-		-
				-	-		-
Melaena	n (%)	1 (1.6)	0	-	-		-
				-	-		-
Nausea	n (%)	1 (1.6)	0	-	-		-
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_74

DATE: 16JUL2024 11:01

Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	p-value[2]	95% CI
Immune system disorders	n (%)	0	1 (2.0)	-	-	-	-
Seasonal allergy	n (%)	0	1 (2.0)	-	-	-	-
Psychiatric disorders	n (%)	0	1 (2.0)	-	-	-	-
Anxiety	n (%)	0	1 (2.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_74

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Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value[2]
Reproductive system and breast disorders	n (%)	1 (1.6)	0	-	-	-	-
Benign prostatic hyperplasia	n (%)	1 (1.6)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_74

DATE: 16JUL2024 11:01

Table Saf_74

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 TEAE	p-value [3]	0.2205
Eye disorders	p-value [3]	0.5337
Neovascular age-related macular degeneration	p-value [3]	0.1321
Visual acuity reduced	p-value [3]	0.5706
Infections and infestations	p-value [3]	0.7781
Investigations	p-value [3]	0.6211
Injury, poisoning and procedural complications	p-value [3]	0.9212
Vascular disorders	p-value [3]	0.9311
Cardiac disorders	p-value [3]	0.5733

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_74

DATE: 16JUL2024 11:01

Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years							
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference	
MedDRA Preferred Term	Statistic	Ranibizumab (N=54)	(Masked Data)[1] (N=62)			95% CI	p-value[2]
At Least 1 Serious TEAE	n (%)	5 (9.3)	6 (9.7)	1.0500 (0.3017, 3.6546)	1.0452 (0.3378, 3.2334)	0.0042 (-0.1026, 0.1109)	0.9391
Respiratory, thoracic and mediastinal disorders	n (%)	2 (3.7)	1 (1.6)	-	-	-	-
Chronic obstructive pulmonary disease	n (%)	0	1 (1.6)	-	-	-	-
Asthma	n (%)	1 (1.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_75

DATE: 16JUL2024 11:06

Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class		Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic					
Respiratory, thoracic and mediastinal disorders						
Pleural effusion	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Cardiac disorders	n (%)	0	2 (3.2)	-	-	-
				-	-	-
Acute myocardial infarction	n (%)	0	1 (1.6)	-	-	-
				-	-	-
Myocardial infarction	n (%)	0	1 (1.6)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:06

Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Infections and infestations	n (%)	0	2 (3.2)	-	-	-
				-	-	-
Clostridium difficile infection	n (%)	0	1 (1.6)	-	-	-
				-	-	-
Pneumonia	n (%)	0	1 (1.6)	-	-	-
				-	-	-
Investigations	n (%)	0	1 (1.6)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:06

Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations						
Intraocular pressure increased	n (%)	0	1 (1.6)	-	-	-
				-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Squamous cell carcinoma of the tongue	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Nervous system disorders	n (%)	1 (1.9)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class		Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic					
Nervous system disorders						
Cerebral infarction	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Renal and urinary disorders	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Nephrolithiasis	n (%)	1 (1.9)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:06

Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years

MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 Serious TEAE	n (%)	11 (18.0)	8 (15.7)	0.8457 (0.3118, 2.2937)	0.8699 (0.3788, 1.9976)	-0.0235 (-0.1623, 0.1154) 0.7429
Infections and infestations	n (%)	3 (4.9)	2 (3.9)	-	-	-
COVID-19	n (%)	1 (1.6)	1 (2.0)	-	-	-
Urinary tract infection	n (%)	0	1 (2.0)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:06

Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years

MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Infections and infestations						
COVID-19 pneumonia	n (%)	1 (1.6)	0	-	-	-
				-	-	-
Pyelonephritis	n (%)	1 (1.6)	0	-	-	-
				-	-	-
Cardiac disorders	n (%)	3 (4.9)	1 (2.0)	-	-	-
				-	-	-
Aortic valve stenosis	n (%)	0	1 (2.0)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:06

Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years

MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Cardiac disorders						
Bundle branch block	n (%)	0	1 (2.0)	-	-	-
				-	-	-
Bundle branch block right	n (%)	1 (1.6)	0	-	-	-
				-	-	-
Cardiac arrest	n (%)	1 (1.6)	0	-	-	-
				-	-	-
Pericardial effusion	n (%)	1 (1.6)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders	n (%)	4 (6.6)	0	-	-	-
				-	-	-
Cerebrovascular accident	n (%)	1 (1.6)	0	-	-	-
				-	-	-
Confusional state	n (%)	1 (1.6)	0	-	-	-
				-	-	-
Embolic stroke	n (%)	1 (1.6)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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DATE: 16JUL2024 11:06

Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders						
Seizure	n (%)	1 (1.6)	0	-	-	-
				-	-	-
Vascular disorders	n (%)	2 (3.3)	1 (2.0)	-	-	-
				-	-	-
Transient ischaemic attack	n (%)	0	1 (2.0)	-	-	-
				-	-	-
Epistaxis	n (%)	1 (1.6)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:06

Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders						
Hypotension	n (%)	1 (1.6)	0	-	-	-
				-	-	-
General disorders and administration site conditions	n (%)	1 (1.6)	1 (2.0)	-	-	-
				-	-	-
Death	n (%)	0	1 (2.0)	-	-	-
				-	-	-
Cardiac death	n (%)	1 (1.6)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_75

DATE: 16JUL2024 11:06

Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years

MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications	n (%)	1 (1.6)	1 (2.0)	-	-	-
Rib fracture	n (%)	0	1 (2.0)	-	-	-
Hip fracture	n (%)	1 (1.6)	0	-	-	-
Metabolism and nutrition disorders	n (%)	1 (1.6)	1 (2.0)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_75

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Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years

MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Metabolism and nutrition disorders						
Hyponatraemia	n (%)	0	1 (2.0)	-	-	-
				-	-	-
Hypokalaemia	n (%)	1 (1.6)	0	-	-	-
				-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	1 (1.6)	1 (2.0)	-	-	-
				-	-	-
Acute leukaemia	n (%)	0	1 (2.0)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_75

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Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder neoplasm	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Musculoskeletal and connective tissue disorders	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Bursitis	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Respiratory, thoracic and mediastinal disorders	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_75

DATE: 16JUL2024 11:06

Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders						
Respiratory failure	n (%)	0	1 (2.0)	- -	- -	- -
Renal and urinary disorders	n (%)	1 (1.6)	0	- -	- -	- -
Haemorrhage urinary tract	n (%)	1 (1.6)	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_75

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Table Saf_75

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2
Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 Serious TEAE	p-value [3]	0.7486

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_75

DATE: 16JUL2024 11:06

Table Saf_76

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value[2]
At Least 1 Related TEAE	n (%)	7 (13.0)	11 (17.7)	1.4482 (0.5185, 4.0449)	1.3687 (0.5708, 3.2819)	0.0478 (-0.0829, 0.1784)	0.4802
Eye disorders	n (%)	5 (9.3)	10 (16.1)	1.8846 (0.6014, 5.9060)	1.7419 (0.6347, 4.7809)	0.0687 (-0.0511, 0.1885)	0.2734
Conjunctival haemorrhage	n (%)	1 (1.9)	7 (11.3)	-	-	-	-
Eye irritation	n (%)	0	2 (3.2)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_76

DATE: 16JUL2024 11:08

Table Saf_76

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Eye disorders						
Corneal abrasion	n (%)	1 (1.9)	1 (1.6)	-	-	-
				-	-	-
Dry eye	n (%)	1 (1.9)	1 (1.6)	-	-	-
				-	-	-
Punctate keratitis	n (%)	1 (1.9)	1 (1.6)	-	-	-
				-	-	-
Iritis	n (%)	0	1 (1.6)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_76

DATE: 16JUL2024 11:08

Table Saf_76

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Eye disorders						
Retinal pigment epithelial tear	n (%)	0	1 (1.6)	-	-	-
				-	-	-
Vitreous floaters	n (%)	0	1 (1.6)	-	-	-
				-	-	-
Conjunctival hyperaemia	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Dry age-related macular degeneration	n (%)	1 (1.9)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_76

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Eye disorders						
Eye pain	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Lacrimation increased	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Subretinal fluid	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Cardiac disorders	n (%)	0	1 (1.6)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_76

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Table Saf_76

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders						
Acute myocardial infarction	n (%)	0	1 (1.6)	-	-	-
				-	-	-
Immune system disorders	n (%)	0	1 (1.6)	-	-	-
				-	-	-
Iodine allergy	n (%)	0	1 (1.6)	-	-	-
				-	-	-
Investigations	n (%)	0	1 (1.6)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:08

Table Saf_76

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations						
Intraocular pressure increased	n (%)	0	1 (1.6)	-	-	-
				-	-	-
Injury, poisoning and procedural complications	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Procedural pain	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Nervous system disorders	n (%)	1 (1.9)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:08

Table Saf_76

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class		Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic					
Nervous system disorders						
Cerebral infarction	n (%)	1 (1.9)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_76

DATE: 16JUL2024 11:08

Table Saf_76

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 Related TEAE	n (%)	2 (3.3)	9 (17.6)	6.3214 (1.2989, 30.7654)	5.3824 (1.2175, 23.7952)	0.1437 (0.0299, 0.2575) 0.0113
Eye disorders	n (%)	1 (1.6)	8 (15.7)	11.1628 (1.3460, 92.5738)	9.5686 (1.2376, 73.9813)	0.1405 (0.0357, 0.2452) 0.0067
Conjunctival haemorrhage	n (%)	1 (1.6)	2 (3.9)	-	-	-
Vitreous floaters	n (%)	0	2 (3.9)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_76

DATE: 16JUL2024 11:08

Table Saf_76

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years

MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Eye disorders						
Vitreous haemorrhage	n (%)	0	2 (3.9)	-	-	-
				-	-	-
Corneal abrasion	n (%)	0	1 (2.0)	-	-	-
				-	-	-
Dry eye	n (%)	0	1 (2.0)	-	-	-
				-	-	-
Photopsia	n (%)	0	1 (2.0)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_76

DATE: 16JUL2024 11:08

Table Saf_76

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years						
MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) [1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	n (%)	0	2 (3.9)	- -	- -	- -
Blood pressure increased	n (%)	0	1 (2.0)	- -	- -	- -
Intraocular pressure increased	n (%)	0	1 (2.0)	- -	- -	- -
Injury, poisoning and procedural complications	n (%)	1 (1.6)	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_76

DATE: 16JUL2024 11:08

Table Saf_76

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study
(Safety Population)

>= 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications						
Procedural pain	n (%)	1 (1.6)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_76

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2
Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 Related TEAE	p-value [3]	0.2939
Eye disorders	p-value [3]	0.4010

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_76

DATE: 16JUL2024 11:08

Table Saf_77

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study (Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) [1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious Related TEAE	n (%)	1 (1.9)	2 (3.2)	-	-	-
Cardiac disorders	n (%)	0	1 (1.6)	-	-	-
Acute myocardial infarction	n (%)	0	1 (1.6)	-	-	-
Investigations	n (%)	0	1 (1.6)	-	-	-
Intraocular pressure increased	n (%)	0	1 (1.6)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_77

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study (Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value
Nervous system disorders	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-
Cerebral infarction	n (%)	1 (1.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years									
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]		
At Least 1 TEAE		n (%)	40 (74.1)	41 (66.1)	0.6833 (0.3057, 1.5275)	0.8927 (0.7037, 1.1326)	-0.0795 (-0.2454, 0.0865) 0.3545		
Eye disorders	Grade 1	n (%)	22 (40.7)	22 (35.5)	0.8000 (0.3772, 1.6968)	0.8710 (0.5471, 1.3864)	-0.0526 (-0.2297, 0.1245) 0.5622		
	Grade 2	n (%)	8 (14.8)	4 (6.5)	0.3966 (0.1124, 1.3995)	0.4355 (0.1388, 1.3663)	-0.0836 (-0.1964, 0.0291) 0.1418		
	Grade 3	n (%)	0	1 (1.6)	-	-	-		
	Grade 4	n (%)	0	0	-	-	-		
	Grade 5	n (%)	0	0	-	-	-		

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Neovascular age-related macular degeneration	Grade 1	n (%)	8 (14.8)	2 (3.2)	0.1917 (0.0388, 0.9459)	0.2177 (0.0483, 0.9817)	-0.1159 (-0.2203, -0.0114) 0.0272
	Grade 2	n (%)	0	2 (3.2)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	2 (3.7)	7 (11.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=54)	(N=62)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	4 (7.4)	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	3 (5.6)	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Subretinal fluid	Grade 1	n (%)	2 (3.7)	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	3 (5.6)	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal haemorrhage	Grade 1	n (%)	3 (5.6)	2 (3.2)	- -	- -	- -
	Grade 2	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=54)	(N=62)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Corneal abrasion	Grade 1	n (%)	0	3 (4.8)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Punctate keratitis	Grade 1	n (%)	1 (1.9)	2 (3.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Vision blurred	Grade 1	n (%)	1 (1.9)	2 (3.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=54)	(N=62)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Vitreous floaters	Grade 1	n (%)	1 (1.9)	2 (3.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Dermatochalasis	Grade 1	n (%)	2 (3.7)	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=54)	(N=62)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Dry eye	Grade 1	n (%)	1 (1.9)	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Eye pain	Grade 1	n (%)	2 (3.7)	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Metamorphopsia	Grade 1	n (%)	2 (3.7)	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Subretinal fibrosis	Grade 1	n (%)	2 (3.7)	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal oedema	Grade 1	n (%)	2 (3.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Eye irritation	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous detachment	Grade 1	n (%)	0	2 (3.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Cataract	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cataract	Grade 1	n (%)	1 (1.9)	1 (1.6)	-	-	-
cortical					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=54)	(N=62)			
Eye disorders							
Conjunctival hyperaemia	Grade 1	n (%)	2 (3.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Detachment of retinal pigment epithelium	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Dry age-related macular degeneration	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cataract nuclear	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
y							
Chorioretinopath	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Conjunctivitis	Grade 1	n (%)	0	1 (1.6)	-	-	-
allergic					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Iritis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Macular hole	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Photopsia	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Retinal pigment epithelial tear	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Retinal tear	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Trichiasis	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous opacities	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blepharitis	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blindness	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Macular oedema	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Macular pigmentation	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Retinal drusen	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous haemorrhage	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	Grade 1	n (%)	6 (11.1)	9 (14.5)	1.3585 (0.4502, 4.0989)	1.3065 (0.4970, 3.4340)	0.0341 (-0.0873, 0.1554) 0.5873
	Grade 2	n (%)	0	2 (3.2)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	0	3 (4.8)	- -	- -	- -
	Grade 2	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=54)	(N=62)	95% CI	95% CI	Difference 95% CI p-value[2]
Investigations							
Blood pressure increased	Grade 1	n (%)	1 (1.9)	2 (3.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure diastolic decreased	Grade 1	n (%)	0	2 (3.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Urine analysis abnormal	Grade 1	n (%)	2 (3.7)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Bacterial test positive	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	0	1 (1.6)	-	-	-
creatinine					-	-	-
increased	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure diastolic increased	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	0	1 (1.6)	-	-	-
triglycerides					-	-	-
increased	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Haematocrit decreased	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Haemoglobin decreased	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=54)	(N=62)	95% CI	95% CI	Difference 95% CI p-value[2]
Investigations							
Laboratory test	Grade 1	n (%)	0	0	-	-	-
abnormal					-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Lymphocyte count decreased	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Monocyte count increased	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Neutrophil count increased	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Urine leukocyte esterase positive	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=54)	(N=62)	95% CI	95% CI	Difference 95% CI p-value[2]
Investigations							
Weight decreased	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cell count increased	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	1 (1.9)	0	-	-	-
creatinine							
abnormal	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea abnormal	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=54)	(N=62)			
Investigations							
Blood uric acid increased	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations	Grade 1	n (%)	3 (5.6)	5 (8.1)	-	-	-
					-	-	-
	Grade 2	n (%)	2 (3.7)	2 (3.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	2 (3.2)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	2 (3.7)	3 (4.8)	- -	- -	- -
	Grade 2	n (%)	1 (1.9)	2 (3.2)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Sinusitis	Grade 1	n (%)	1 (1.9)	2 (3.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Bronchitis	Grade 1	n (%)	1 (1.9)	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Clostridium difficile infection	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Conjunctivitis	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Upper respiratory tract infection	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class	Maximum CTCAE		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference	
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=54)	(Masked Data)[1] (N=62)			95% CI	p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	3 (5.6)	5 (8.1)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (1.9)	1 (1.6)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Injury, poisoning and procedural complications							
Fall	Grade 1	n (%)	2 (3.7)	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications	Grade	n (%)					
Procedural pain	Grade 1	n (%)	1 (1.9)	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Contusion	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Face injury	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Facial bones fracture	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Head injury	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Skin abrasion	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Tooth fracture	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Rib fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade	n (%)					
Nervous system disorders	Grade 1	n (%)	3 (5.6)	2 (3.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Headache	Grade 1	n (%)	2 (3.7)	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Dizziness	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Parkinson's disease	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebral infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Dementia	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders	Grade 1	n (%)	2 (3.7)	3 (4.8)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Metabolism and nutrition disorders							
Hyperlipidaemia	Grade 1	n (%)	1 (1.9)	2 (3.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Vitamin D deficiency	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Diabetes mellitus	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=54)	(N=62)			
Metabolism and nutrition disorders							
Glucose tolerance impaired	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	1 (1.9)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (1.9)	2 (3.2)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (1.9)	1 (1.6)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of skin	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	2 (3.2)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of the oral cavity	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (1.6)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acrochordon	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder cancer recurrent	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of the tongue	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	1 (1.9)	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade	n (%)					
Vascular disorders	Grade 1	n (%)	2 (3.7)	2 (3.2)	-	-	-
					-	-	-
	Grade 2	n (%)	2 (3.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Essential hypertension	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypertension	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hot flush	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypotension	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Venous occlusion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Respiratory, thoracic and mediastinal disorders	Grade 1	n (%)	1 (1.9)	0	-	-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-	-
	Grade 3	n (%)	1 (1.9)	1 (1.6)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Cough	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Epistaxis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Asthma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Nasal congestion	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Oropharyngeal pain	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pleural effusion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Cardiac disorders	Grade 1	n (%)	0	1 (1.6)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	1 (1.6)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	1 (1.6)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Acute myocardial infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Coronary artery disease	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Myocardial infarction	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	1 (1.6)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	2 (3.2)	-	-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Ligament sprain	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Plantar fasciitis	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)	1 (1.9)	2 (3.2)				
Immune system disorders	Grade 1	n (%)	1 (1.9)	2 (3.2)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Allergy to arthropod bite	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Iodine allergy	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Allergic sinusitis	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (1.9)	1 (1.6)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Anxiety	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Stress	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Renal and urinary disorders	Grade 1	n (%)	1 (1.9)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (1.9)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Haematuria	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Nephrolithiasis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Reproductive system and breast disorders	Grade 1	n (%)	0	1 (1.6)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Reproductive system and breast disorders							
Prostatomegaly	Grade 1	n (%)	0	1 (1.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	0	1 (1.6)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders Tinea cruris							
	Grade 1	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)						
Blood and lymphatic system disorders	Grade 1	n (%)	1 (1.9)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Lymphadenopathy	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Gastrointestinal disorders	Grade 1	n (%)	1 (1.9)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Nausea	Grade 1	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>= 80 years									
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]		
At Least 1 TEAE		n (%)	45 (73.8)	41 (80.4)	1.4578 (0.5949, 3.5722)	1.0898 (0.8905, 1.3336)	0.0662 (-0.0889, 0.2213) 0.4106		
Eye disorders	Grade 1	n (%)	19 (31.1)	17 (33.3)	1.1053 (0.4989, 2.4484)	1.0702 (0.6247, 1.8335)	0.0219 (-0.1520, 0.1958) 0.8060		
	Grade 2	n (%)	10 (16.4)	6 (11.8)	0.6800 (0.2289, 2.0197)	0.7176 (0.2800, 1.8396)	-0.0463 (-0.1745, 0.0820) 0.4877		
	Grade 3	n (%)	1 (1.6)	0	-	-	-		
	Grade 4	n (%)	0	0	-	-	-		
	Grade 5	n (%)	0	0	-	-	-		

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	5 (8.2)	1 (2.0)	- -	- -	- -
	Grade 2	n (%)	5 (8.2)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Eye disorders								
Neovascular age-related macular degeneration	Grade 1	n (%)	2 (3.3)	4 (7.8)	2.5106 (0.4406, 14.3054)	2.3922 (0.4566, 12.5326)	0.0456 (-0.0406, 0.1319) 0.2875	
	Grade 2	n (%)	2 (3.3)	1 (2.0)	- -	- -	- -	
	Grade 3	n (%)	0	0	- -	- -	- -	
	Grade 4	n (%)	0	0	- -	- -	- -	
	Grade 5	n (%)	0	0	- -	- -	- -	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Dry eye	Grade 1	n (%)	3 (4.9)	2 (3.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal haemorrhage	Grade 1	n (%)	3 (4.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	2 (3.3)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	0	3 (5.9)	- -	- -	- -
	Grade 2	n (%)	1 (1.6)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Posterior capsule opacification	Grade 1	n (%)	2 (3.3)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>= 80 years							
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Eye disorders							
Vitreous floaters	Grade 1	n (%)	0	3 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>= 80 years							
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Eye disorders							
Cystoid macular oedema	Grade 1	n (%)	2 (3.3)	1 (2.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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>= 80 years							
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Eye disorders							
Hordeolum	Grade 1	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>= 80 years							
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Eye disorders							
Retinal degeneration	Grade 1	n (%)	2 (3.3)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous detachment	Grade 1	n (%)	2 (3.3)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Cataract nuclear	Grade 1	n (%)	0	2 (3.9)	-	-	-
							-
	Grade 2	n (%)	0	0	-	-	-
							-
	Grade 3	n (%)	0	0	-	-	-
							-
	Grade 4	n (%)	0	0	-	-	-
							-
	Grade 5	n (%)	0	0	-	-	-
							-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Corneal abrasion	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=61)	(N=51)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Eye pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	2 (3.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Subretinal fluid	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous haemorrhage	Grade 1	n (%)	0	2 (3.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cataract	Grade 1	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Macular scar	Grade 1	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal pigmentation	Grade 1	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Metamorphopsia	Grade 1	n (%)	2 (3.3)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Retinal vein occlusion	Grade 1	n (%)	2 (3.3)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Angle closure glaucoma	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Choroidal neovascularisation	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Dacryostenosis acquired	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Dermatochalasis	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eye swelling	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Iridocyclitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Photopsia	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Subretinal fibrosis	Grade 1	n (%)	0	1 (2.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Dry age-related macular degeneration	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Entropion	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Exposure	Grade 1	n (%)	1 (1.6)	0	-	-	-
keratitis					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eyelid ptosis	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Foveal degeneration	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Macular fibrosis	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Meibomian gland dysfunction	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Punctate keratitis	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal detachment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Retinal oedema	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal tear	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Vision blurred	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations	Grade 1	n (%)	5 (8.2)	3 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	2 (3.3)	4 (7.8)	-	-	-
					-	-	-
	Grade 3	n (%)	2 (3.3)	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (2.0)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19	Grade 1	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (2.0)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	2 (3.3)	0	- -	- -	- -
	Grade 2	n (%)	0	2 (3.9)	- -	- -	- -
	Grade 3	n (%)	0	1 (2.0)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Acute sinusitis	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Fungal infection	Grade 1	n (%)	0	1 (2.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Influenza	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Anogenital warts	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Bronchitis	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19 pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Cellulitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Herpes zoster	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Pyelonephritis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Sepsis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Investigations	Grade 1	n (%)	6 (9.8)	7 (13.7)	1.4583 (0.4571, 4.6531)	1.3954 (0.5006, 3.8894)	0.0389 (-0.0815, 0.1593)	0.5241
	Grade 2	n (%)	1 (1.6)	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	1 (1.6)	3 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Urine analysis abnormal	Grade 1	n (%)	0	2 (3.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure increased	Grade 1	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Bacterial test positive	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure diastolic decreased	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Protein urine present	Grade 1	n (%)	0	1 (2.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Basophil count increased	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Eosinophil count increased	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Haematocrit decreased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Haemoglobin decreased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Neutrophil count increased	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Platelet count decreased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cell count decreased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cells urine positive	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cell count increased	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade	n (%)					
Vascular disorders	Grade 1	n (%)	3 (4.9)	3 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	2 (3.3)	0	-	-	-
					-	-	-
	Grade 3	n (%)	2 (3.3)	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Syncope	Grade 1	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypotension	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Dizziness	Grade 1	n (%)	2 (3.3)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Essential hypertension	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Transient ischaemic attack	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Aortic arteriosclerosis	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Epistaxis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypertension	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Pulmonary congestion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Cardiac disorders	Grade 1	n (%)	0	1 (2.0)	-	-	-	-
	Grade 2	n (%)	2 (3.3)	3 (5.9)	-	-	-	-
	Grade 3	n (%)	1 (1.6)	1 (2.0)	-	-	-	-
	Grade 4	n (%)	1 (1.6)	0	-	-	-	-
	Grade 5	n (%)	1 (1.6)	0	-	-	-	-

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Atrial fibrillation	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	2 (3.3)	2 (3.9)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Cardiac failure congestive	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Pericardial effusion	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Aortic valve stenosis	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Arrhythmia	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Bradycardia	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Bundle branch block	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Cardiac disorders							
Bundle branch block right	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Cardiac arrest	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	1 (1.6)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	2 (3.3)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	2 (3.3)	3 (5.9)	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Fall	Grade 1	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Head injury	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Rib fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Skin laceration	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Hip fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Joint injury	Grade 1	n (%)	1 (1.6)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Procedural pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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DATE: 16JUL2024 11:11

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Traumatic haematoma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders	Grade 1	n (%)	2 (3.3)	3 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	2 (3.9)	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Haematuria	Grade 1	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Cystitis	Grade 1	n (%)	0	2 (3.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Dysuria	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Urinary tract infection	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Acute kidney injury	Grade 1	n (%)	1 (1.6)	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Bladder diverticulum	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Haemorrhage urinary tract	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Renal cyst	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Renal tubular necrosis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Urinary bladder haemorrhage	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Urinary retention	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Metabolism and nutrition disorders	Grade 1	n (%)	4 (6.6)	1 (2.0)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (1.6)	2 (3.9)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Vitamin D deficiency	Grade 1	n (%)	1 (1.6)	1 (2.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Dyslipidaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hyponatraemia	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	1 (2.0)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Dehydration	Grade 1	n (%)	1 (1.6)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hyperkalaemia	Grade 1	n (%)	1 (1.6)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypokalaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypomagnesaemia	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Malnutrition	Grade 1	n (%)	1 (1.6)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)						
Nervous system disorders	Grade 1	n (%)	1 (1.6)	1 (2.0)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	4 (6.6)	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Migraine	Grade 1	n (%)	0	1 (2.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebral small vessel ischaemic disease	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebrovascular accident	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Confusional state	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Embololic stroke	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Facial paralysis	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Metabolic encephalopathy	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Sciatica	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Seizure	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Tremor	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	2 (3.3)	2 (3.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acute leukaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Basal cell carcinoma	Grade 1	n (%)	0	1 (2.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Keratoacanthoma	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder cancer	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder neoplasm	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Eye naevus	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Skin cancer	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
General disorders and administration site conditions	Grade 1	n (%)	2 (3.3)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (1.6)	1 (2.0)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	1 (1.6)	1 (2.0)	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Asthenia	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Death	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (2.0)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Cardiac death	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	1 (1.6)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Gait inability	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Peripheral swelling	Grade 1	n (%)	1 (1.6)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Pyrexia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	2 (3.3)	2 (3.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Skin lesion	Grade 1	n (%)	1 (1.6)	1 (2.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders Ecchymosis							
	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders Eczema							
	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Rash	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	3 (4.9)	1 (2.0)	-	-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	1 (2.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Musculoskeletal and connective tissue disorders							
Bursitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Hand fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Joint swelling	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Pain in extremity	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Respiratory, thoracic and mediastinal disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	3 (4.9)	0	-	-	-	-
	Grade 3	n (%)	1 (1.6)	1 (2.0)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Respiratory failure	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders Atelectasis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Cough	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Hypoxia	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pleural effusion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pulmonary fibrosis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pulmonary oedema	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Blood and lymphatic system disorders	Grade 1	n (%)	1 (1.6)	2 (3.9)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Anaemia	Grade 1	n (%)	0	1 (2.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Microcytic anaemia	Grade 1	n (%)	0	1 (2.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Blood loss anaemia	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders	Grade 1	n (%)	2 (3.3)	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Small intestinal obstruction	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Gastroesophageal reflux disease	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Melaena	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Nausea	Grade 1	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

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Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Immune system disorders	Grade 1	n (%)	0	1 (2.0)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Seasonal allergy	Grade 1	n (%)	0	1 (2.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	1 (2.0)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Anxiety	Grade 1	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Reproductive system and breast disorders	Grade 1	n (%)	1 (1.6)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Date of data extract: 26AUG2020

Table Saf_78

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Reproductive system and breast disorders							
Benign prostatic hyperplasia	Grade 1	n (%)	1 (1.6)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic p-value [3]	Interaction
At Least 1 TEAE			0.2205
Eye disorders	Grade 1	p-value [3]	0.5481
Neovascular age-related macular degeneration	Grade 2	p-value [3]	0.6549
	Grade 1	p-value [3]	0.0235
Investigations	Grade 1	p-value [3]	0.9660

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_78

DATE: 16JUL2024 11:11

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
At Least 1 Serious TEAE		n (%)	5 (9.3)	6 (9.7)	1.0500 (0.3017, 3.6546)	1.0452 (0.3378, 3.2334)	0.0042 (-0.1026, 0.1109) 0.9391	
Respiratory, thoracic and mediastinal disorders	Grade 1	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 2	n (%)	1 (1.9)	0	-	-	-	
					-	-	-	
	Grade 3	n (%)	1 (1.9)	1 (1.6)	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	0	0	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (1.6)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Asthma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pleural effusion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Cardiac disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	1 (1.6)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	1 (1.6)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Acute myocardial infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Myocardial infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (1.6)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Infections and infestations	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	2 (3.2)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Clostridium difficile infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Investigations	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations Intraocular pressure increased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.6)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (1.9)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of the tongue	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	1 (1.9)	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Nervous system disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	1 (1.9)	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebral infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Renal and urinary disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (1.9)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data)[1] (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Nephrolithiasis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
At Least 1 Serious TEAE		n (%)	11 (18.0)	8 (15.7)	0.8457 (0.3118, 2.2937)	0.8699 (0.3788, 1.9976)	-0.0235 (-0.1623, 0.1154) 0.7429	
Infections and infestations	Grade 1	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 2	n (%)	1 (1.6)	0	-	-	-	
					-	-	-	
	Grade 3	n (%)	2 (3.3)	1 (2.0)	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	0	1 (2.0)	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (2.0)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	1 (2.0)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19 pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Pyelonephritis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Cardiac disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (1.6)	1 (2.0)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	1 (1.6)	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	1 (1.6)	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Aortic valve stenosis	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (2.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Bundle branch block	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Cardiac disorders							
Bundle branch block right	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders	Grade 1	n (%)	0	0	-	-	-
Cardiac arrest	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	1 (1.6)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Pericardial effusion	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	1 (1.6)	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Nervous system disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	3 (4.9)	0	-	-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebrovascular accident	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	1 (1.6)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Confusional state	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	1 (1.6)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Embololic stroke	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Seizure	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	2 (3.3)	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Transient ischaemic attack	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Epistaxis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Vascular disorders							
Hypotension	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

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Protocol ONS-5010-002

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Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
General disorders and administration site conditions	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	1 (1.6)	1 (2.0)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Death	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (2.0)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Cardiac death	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	1 (1.6)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (1.6)	1 (2.0)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Rib fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Hip fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (1.6)	1 (2.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hyponatraemia	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	1 (2.0)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypokalaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acute leukaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder neoplasm	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Bursitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Respiratory, thoracic and mediastinal disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Respiratory failure	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Date of data extract: 26AUG2020

Table Saf_79

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Haemorrhage urinary tract	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.6)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-2 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Interaction
MedDRA Preferred Term		p-value [3]	
At Least 1 Serious TEAE			0.7486

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_79

DATE: 16JUL2024 11:14

Table Saf_80

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study (Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	3 (5.6)	0	-	-	-	-
Eye disorders	n (%)	2 (3.7)	0	-	-	-	-
Retinal oedema	n (%)	1 (1.9)	0	-	-	-	-
Subretinal fluid	n (%)	1 (1.9)	0	-	-	-	-
Visual acuity reduced	n (%)	1 (1.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_80

DATE: 10JUL2024 15:10

Table Saf_80

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study (Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Nervous system disorders	n (%)	1 (1.9)	0	-	-	-
				-	-	-
Cerebral infarction	n (%)	1 (1.9)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_80

DATE: 10JUL2024 15:10

Table Saf_80

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data)[1] (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	2 (3.3)	2 (3.9)	-	-	-	-
				-	-	-	-
General disorders and administration site conditions	n (%)	0	2 (3.9)	-	-	-	-
Asthenia	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Death	n (%)	0	1 (2.0)	-	-	-	-
				-	-	-	-
Cardiac disorders	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_80

DATE: 10JUL2024 15:10

Table Saf_80

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-2 Study (Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Cardiac disorders							
Cardiac arrest	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Respiratory, thoracic and mediastinal disorders	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-
Pulmonary fibrosis	n (%)	1 (1.6)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_80

DATE: 10JUL2024 15:10

Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
At Least 1 TEAE	n (%)	36 (78.3)	33 (71.7)	0.7051 (0.2727, 1.8235)	0.9167 (0.7234, 1.1616)	-0.0652 (-0.2417, 0.1112)	0.4725
Eye disorders	n (%)	24 (52.2)	24 (52.2)	1.0000 (0.4413, 2.2663)	1.0000 (0.6762, 1.4789)	0.0000 (-0.2041, 0.2041)	>0.9999
Neovascular age-related macular degeneration	n (%)	4 (8.7)	5 (10.9)	1.2805 (0.3210, 5.1072)	1.2500 (0.3583, 4.3614)	0.0217 (-0.0996, 0.1431)	0.7271
Visual acuity reduced	n (%)	6 (13.0)	2 (4.3)	0.3030 (0.0578, 1.5883)	0.3333 (0.0709, 1.5662)	-0.0870 (-0.2007, 0.0268)	0.1410

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_81

DATE: 16JUL2024 11:17

Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Vitreous floaters	n (%)	1 (2.2)	4 (8.7)	-	-	-	-
				-	-	-	-
Subretinal fluid	n (%)	2 (4.3)	3 (6.5)	-	-	-	-
				-	-	-	-
Corneal abrasion	n (%)	1 (2.2)	3 (6.5)	-	-	-	-
				-	-	-	-
Cataract	n (%)	2 (4.3)	2 (4.3)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Dry eye	n (%)	2 (4.3)	2 (4.3)	-	-	-	-
				-	-	-	-
Eye pain	n (%)	2 (4.3)	2 (4.3)	-	-	-	-
				-	-	-	-
Conjunctival haemorrhage	n (%)	1 (2.2)	2 (4.3)	2.0455 (0.1790, 23.3776)	2.0000 (0.1878, 21.2968)	0.0217 (-0.0507, 0.0942)	0.5594
Dermatochalasis	n (%)	2 (4.3)	1 (2.2)	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) [1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value [2]
Eye disorders							
Retinal haemorrhage		n (%)	2 (4.3)	1 (2.2)	-	-	-
					-	-	-
Cataract nuclear		n (%)	0	2 (4.3)	-	-	-
					-	-	-
Photopsia		n (%)	0	2 (4.3)	-	-	-
					-	-	-
Vitreous haemorrhage		n (%)	0	2 (4.3)	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Cystoid macular oedema		n (%)	1 (2.2)	1 (2.2)	-	-	-
					-	-	-
Hordeolum		n (%)	1 (2.2)	1 (2.2)	-	-	-
					-	-	-
Punctate keratitis		n (%)	1 (2.2)	1 (2.2)	-	-	-
					-	-	-
Posterior capsule opacification		n (%)	2 (4.3)	0	-	-	-
					-	-	-

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(Safety Population)

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MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Retinal oedema	n (%)	2 (4.3)	0	-	-	-	-
				-	-	-	-
Vision blurred	n (%)	2 (4.3)	0	-	-	-	-
				-	-	-	-
Angle closure glaucoma	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Chorioretinopathy	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Choroidal neovascularisation		n (%)	0	1 (2.2)	-	-	-
					-	-	-
Conjunctivitis allergic		n (%)	0	1 (2.2)	-	-	-
					-	-	-
Eye irritation		n (%)	0	1 (2.2)	-	-	-
					-	-	-
Iridocyclitis		n (%)	0	1 (2.2)	-	-	-
					-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Macular scar	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Retinal pigment epithelial tear	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Retinal pigmentation	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Trichiasis	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Conjunctival hyperaemia		n (%)	1 (2.2)	0	-	-	-
					-	-	-
Detachment of retinal pigment epithelium		n (%)	1 (2.2)	0	-	-	-
					-	-	-
Dry age-related macular degeneration		n (%)	1 (2.2)	0	-	-	-
					-	-	-
Entropion		n (%)	1 (2.2)	0	-	-	-
					-	-	-

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MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Exposure keratitis	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Eyelid ptosis	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Macular oedema	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Metamorphopsia		n (%)	1 (2.2)	0	-	-	-
					-	-	-
Retinal degeneration		n (%)	1 (2.2)	0	-	-	-
					-	-	-
Retinal detachment		n (%)	1 (2.2)	0	-	-	-
					-	-	-
Retinal drusen		n (%)	1 (2.2)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Retinal tear		n (%)	1 (2.2)	0	-	-	-
					-	-	-
Retinal vein occlusion		n (%)	1 (2.2)	0	-	-	-
					-	-	-
Subretinal fibrosis		n (%)	1 (2.2)	0	-	-	-
					-	-	-
Vitreous detachment		n (%)	1 (2.2)	0	-	-	-
					-	-	-

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(Safety Population)

Male							
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Investigations	n (%)	8 (17.4)	9 (19.6)	1.1554 (0.4025, 3.3166)	1.1250 (0.4759, 2.6592)	0.0217 (-0.1368, 0.1803)	0.7893
Blood pressure increased	n (%)	1 (2.2)	2 (4.3)	-	-	-	-
Intraocular pressure increased	n (%)	1 (2.2)	2 (4.3)	-	-	-	-
Urine analysis abnormal	n (%)	0	2 (4.3)	-	-	-	-

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Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Bacterial test positive	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Blood pressure diastolic decreased	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Blood pressure diastolic increased	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Protein urine present	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Weight decreased	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Basophil count increased	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Blood creatinine abnormal	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Blood urea abnormal	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Eosinophil count increased	n (%)	1 (2.2)	0	-	-	-	-
Haematocrit decreased	n (%)	1 (2.2)	0	-	-	-	-
Haemoglobin decreased	n (%)	1 (2.2)	0	-	-	-	-
Neutrophil count increased	n (%)	1 (2.2)	0	-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Platelet count decreased	n (%)	1 (2.2)	0	-	-	-	-
Red blood cell count decreased	n (%)	1 (2.2)	0	-	-	-	-
White blood cell count increased	n (%)	1 (2.2)	0	-	-	-	-
White blood cells urine positive	n (%)	1 (2.2)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_81

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Infections and infestations	n (%)	5 (10.9)	7 (15.2)	1.4718 (0.4308, 5.0279)	1.4000 (0.4791, 4.0914)	0.0435 (-0.0939, 0.1808)	0.5380
COVID-19	n (%)	2 (4.3)	2 (4.3)	-	-	-	-
Pneumonia	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
Clostridium difficile infection	n (%)	0	1 (2.2)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Infections and infestations							
Conjunctivitis	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Influenza	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Urinary tract infection	n (%)	0	1 (2.2)	NE (NE, NE)	NE (NE, NE)	0.0217 (-0.0204, 0.0639)	0.3173
Anogenital warts	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Infections and infestations							
COVID-19 pneumonia	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Cellulitis	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Pyelonephritis	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Sepsis	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Infections and infestations							
Sinusitis	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Injury, poisoning and procedural complications	n (%)	5 (10.9)	3 (6.5)	0.5721 (0.1284, 2.5484)	0.6000 (0.1522, 2.3654)	-0.0435 (-0.1583, 0.0713)	0.4617
Fall	n (%)	3 (6.5)	1 (2.2)	-	-	-	-
				-	-	-	-
Contusion	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications							
Skin abrasion	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Skin laceration	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Joint injury	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Procedural pain	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications							
Traumatic haematoma	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	5 (10.9)	3 (6.5)	-	-	-	-
				-	-	-	-
Basal cell carcinoma	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Keratoacanthoma	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
	Squamous cell carcinoma of skin	n (%)	0	1 (2.2)	-	-	-
	Acrochordon	n (%)	1 (2.2)	0	-	-	-
	Bladder cancer	n (%)	1 (2.2)	0	-	-	-
	Bladder neoplasm	n (%)	1 (2.2)	0	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Eye naevus	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Skin cancer	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Squamous cell carcinoma of the tongue	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Nervous system disorders	n (%)	6 (13.0)	2 (4.3)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Dizziness	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Migraine	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Cerebral small vessel ischaemic disease	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Cerebrovascular accident	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Confusional state	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Facial paralysis	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Headache	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Metabolic encephalopathy	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Sciatica	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Seizure	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Metabolism and nutrition disorders	n (%)	2 (4.3)	4 (8.7)	-	-	-	-
				-	-	-	-
Vitamin D deficiency	n (%)	0	2 (4.3)	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Metabolism and nutrition disorders							
Dyslipidaemia	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Hyperlipidaemia	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Glucose tolerance impaired	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Hyperkalaemia	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders	n (%)	3 (6.5)	3 (6.5)	-	-	-	-
Cystitis	n (%)	0	2 (4.3)	-	-	-	-
Dysuria	n (%)	0	1 (2.2)	-	-	-	-
Bladder diverticulum	n (%)	1 (2.2)	0	-	-	-	-

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Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders							
Haematuria	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Haemorrhage urinary tract	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Nephrolithiasis	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Renal cyst	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders							
Renal tubular necrosis	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Urinary bladder haemorrhage	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Urinary retention	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Vascular disorders	n (%)	4 (8.7)	2 (4.3)	0.4773 (0.0830, 2.7444)	0.5000 (0.0963, 2.5968)	-0.0435 (-0.1440, 0.0570)	0.4010

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_81

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) [1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value [2]
Vascular disorders							
Hypotension		n (%)	1 (2.2)	1 (2.2)	-	-	-
					-	-	-
Transient ischaemic attack		n (%)	0	1 (2.2)	-	-	-
					-	-	-
Dizziness		n (%)	1 (2.2)	0	-	-	-
					-	-	-
Hypertension		n (%)	1 (2.2)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Vascular disorders							
Pulmonary congestion		n (%)	1 (2.2)	0	-	-	-
					-	-	-
Venous occlusion		n (%)	1 (2.2)	0	-	-	-
					-	-	-
Cardiac disorders							
		n (%)	1 (2.2)	4 (8.7)	-	-	-
					-	-	-
Acute myocardial infarction		n (%)	0	1 (2.2)	-	-	-
					-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Cardiac disorders							
Aortic valve stenosis	n (%)	0	0	1 (2.2)	-	-	-
					-	-	-
Arrhythmia	n (%)	0	0	1 (2.2)	-	-	-
					-	-	-
Bradycardia	n (%)	0	0	1 (2.2)	-	-	-
					-	-	-
Bundle branch block	n (%)	0	0	1 (2.2)	-	-	-
					-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Cardiac disorders							
Atrial fibrillation	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
General disorders and administration site conditions	n (%)	2 (4.3)	2 (4.3)	-	-	-	-
				-	-	-	-
Asthenia	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Death	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
General disorders and administration site conditions							
Gait inability	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Pyrexia	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Respiratory, thoracic and mediastinal disorders	n (%)	2 (4.3)	2 (4.3)	-	-	-	-
				-	-	-	-
Chronic obstructive pulmonary disease	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Cough	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Epistaxis	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Respiratory failure	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Atelectasis	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Hypoxia	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Nasal congestion	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Oropharyngeal pain	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Pleural effusion	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pulmonary oedema	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Skin and subcutaneous tissue disorders	n (%)	0	2 (4.3)	-	-	-	-
				-	-	-	-
Eczema	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Skin lesion	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Blood and lymphatic system disorders	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
Microcytic anaemia	n (%)	0	1 (2.2)	-	-	-	-
Lymphadenopathy	n (%)	1 (2.2)	0	-	-	-	-
Musculoskeletal and connective tissue disorders	n (%)	1 (2.2)	1 (2.2)	-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk
MedDRA System Organ Class			ONS-5010				Difference
MedDRA Preferred Term	Statistic	Ranibizumab (N=46)	(Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI
p-value[2]							
Musculoskeletal and connective tissue disorders							
Back pain	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Joint swelling	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Reproductive system and breast disorders							
Prostatomegaly	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
				-	-	-	-
				-	-	-	-

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(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Reproductive system and breast disorders							
Benign prostatic hyperplasia	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Immune system disorders	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Seasonal allergy	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
At Least 1 TEAE	n (%)	49 (71.0)	49 (73.1)	1.1111 (0.5249, 2.3519)	1.0299 (0.8354, 1.2696)	0.0212 (-0.1295, 0.1719) 0.7838	
Eye disorders	n (%)	36 (52.2)	26 (38.8)	0.5813 (0.2940, 1.1492)	0.7438 (0.5106, 1.0834)	-0.1337 (-0.2995, 0.0322) 0.1190	
Neovascular age-related macular degeneration	n (%)	8 (11.6)	4 (6.0)	0.4841 (0.1386, 1.6911)	0.5149 (0.1627, 1.6298)	-0.0562 (-0.1507, 0.0382) 0.2494	
Visual acuity reduced	n (%)	11 (15.9)	1 (1.5)	0.0799 (0.0100, 0.6377)	0.0936 (0.0124, 0.7053)	-0.1445 (-0.2356, -0.0534) 0.0031	

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	n (%)	2 (2.9)	8 (11.9)	4.5424 (0.9277, 22.2414)	4.1194 (0.9077, 18.6956)	0.0904 (0.0033, 0.1776)	0.0442
Retinal haemorrhage	n (%)	6 (8.7)	2 (3.0)	-	-	-	-
Vitreous detachment	n (%)	1 (1.4)	3 (4.5)	-	-	-	-
Dry eye	n (%)	3 (4.3)	1 (1.5)	-	-	-	-

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Metamorphopsia	n (%)	3 (4.3)	1 (1.5)	-	-	-	-
				-	-	-	-
Subretinal fluid	n (%)	3 (4.3)	1 (1.5)	-	-	-	-
				-	-	-	-
Punctate keratitis	n (%)	1 (1.4)	2 (3.0)	-	-	-	-
				-	-	-	-
Subretinal fibrosis	n (%)	1 (1.4)	2 (3.0)	-	-	-	-
				-	-	-	-

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Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Corneal abrasion	n (%)	0	2 (3.0)	-	-	-	-
				-	-	-	-
Vision blurred	n (%)	0	2 (3.0)	-	-	-	-
				-	-	-	-
Cataract cortical	n (%)	1 (1.4)	1 (1.5)	-	-	-	-
				-	-	-	-
Posterior capsule opacification	n (%)	1 (1.4)	1 (1.5)	-	-	-	-
				-	-	-	-

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Retinal degeneration		n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-
Dry age-related macular degeneration		n (%)	2 (2.9)	0	-	-	-
					-	-	-
Retinal oedema		n (%)	2 (2.9)	0	-	-	-
					-	-	-
Cataract nuclear		n (%)	0	1 (1.5)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_81

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Dacryostenosis acquired		n (%)	0	1 (1.5)	-	-	-
					-	-	-
Dermatochalasis		n (%)	0	1 (1.5)	-	-	-
					-	-	-
Eye irritation		n (%)	0	1 (1.5)	-	-	-
					-	-	-
Eye pain		n (%)	0	1 (1.5)	-	-	-
					-	-	-

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Eye swelling	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Iritis	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Macular hole	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Retinal tear	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Vitreous floaters	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Vitreous opacities	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Blepharitis	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Blindness	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Conjunctival hyperaemia	n (%)	1 (1.4)	0		-	-	-
					-	-	-
Cystoid macular oedema	n (%)	1 (1.4)	0		-	-	-
					-	-	-
Detachment of retinal pigment epithelium	n (%)	1 (1.4)	0		-	-	-
					-	-	-
Foveal degeneration	n (%)	1 (1.4)	0		-	-	-
					-	-	-

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Hordeolum	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Macular fibrosis	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Macular pigmentation	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Macular scar	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Meibomian gland dysfunction	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Retinal pigmentation	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Retinal vein occlusion	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Vitreous haemorrhage	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	9 (13.0)	11 (16.4)	1.3095 (0.5048, 3.3971)	1.2587 (0.5576, 2.8416)	0.0337 (-0.0853, 0.1528)	0.5799
Urinary tract infection	n (%)	5 (7.2)	7 (10.4)	1.4933 (0.4496, 4.9604)	1.4418 (0.4812, 4.3197)	0.0320 (-0.0634, 0.1274)	0.5121
Bronchitis	n (%)	2 (2.9)	1 (1.5)	-	-	-	-
				-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Infections and infestations							
COVID-19	n (%)	2 (2.9)	1 (1.5)	-	-	-	-
				-	-	-	-
Sinusitis	n (%)	0	2 (3.0)	-	-	-	-
				-	-	-	-
Acute sinusitis	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Fungal infection	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Infections and infestations							
Upper respiratory tract infection	n (%)	0	1 (1.5)	-	-	-	-
Herpes zoster	n (%)	1 (1.4)	0	-	-	-	-
Investigations	n (%)	5 (7.2)	9 (13.4)	1.9862 (0.6292, 6.2698)	1.8537 (0.6550, 5.2459)	0.0619 (-0.0402, 0.1639)	0.2370
Intraocular pressure increased	n (%)	0	5 (7.5)	-	-	-	-

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood pressure diastolic decreased	n (%)	0	2 (3.0)	-	-	-	-
Blood pressure increased	n (%)	1 (1.4)	1 (1.5)	-	-	-	-
Urine analysis abnormal	n (%)	2 (2.9)	0	-	-	-	-
Bacterial test positive	n (%)	0	1 (1.5)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood creatinine increased	n (%)	0	1 (1.5)	-	-	-	-
Blood triglycerides increased	n (%)	0	1 (1.5)	-	-	-	-
Haematocrit decreased	n (%)	0	1 (1.5)	-	-	-	-
Haemoglobin decreased	n (%)	0	1 (1.5)	-	-	-	-

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Laboratory test abnormal	n (%)	0	1 (1.5)	-	-	-	-
Lymphocyte count decreased	n (%)	0	1 (1.5)	-	-	-	-
Monocyte count increased	n (%)	0	1 (1.5)	-	-	-	-
Neutrophil count increased	n (%)	0	1 (1.5)	-	-	-	-

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Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Urine leukocyte esterase positive	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
White blood cell count increased	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Blood uric acid increased	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Red blood cells urine positive	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

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(Safety Population)

Female							
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	
MedDRA Preferred Term	Statistic	Ranibizumab (N=69)	(Masked Data)[1] (N=67)			p-value[2]	
Injury, poisoning and procedural complications	n (%)	4 (5.8)	8 (11.9)	2.2034 (0.6307, 7.6975)	2.0597 (0.6508, 6.5192)	0.0614 (-0.0338, 0.1567) 0.2083	
Fall	n (%)	1 (1.4)	2 (3.0)	-	-	-	
Head injury	n (%)	0	2 (3.0)	-	-	-	
Procedural pain	n (%)	1 (1.4)	1 (1.5)	-	-	-	

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MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications							
Rib fracture	n (%)	1 (1.4)	1 (1.5)	-	-	-	-
				-	-	-	-
Face injury	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Facial bones fracture	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Tooth fracture	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_81

DATE: 16JUL2024 11:17

Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications							
Hip fracture	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Vascular disorders	n (%)	7 (10.1)	4 (6.0)	0.5624 (0.1567, 2.0176)	0.5885 (0.1805, 1.9182)	-0.0417 (-0.1328, 0.0493)	0.3738
Essential hypertension	n (%)	1 (1.4)	2 (3.0)	-	-	-	-
				-	-	-	-
Syncope	n (%)	2 (2.9)	1 (1.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Vascular disorders							
Hypertension	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Aortic arteriosclerosis	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Dizziness	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Epistaxis	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Vascular disorders							
Hot flush	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Hypotension	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Cardiac disorders	n (%)	4 (5.8)	4 (6.0)	-	-	-	-
				-	-	-	-
Atrial fibrillation	n (%)	1 (1.4)	2 (3.0)	-	-	-	-
				-	-	-	-

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Cardiac disorders							
Cardiac failure congestive	n (%)	2 (2.9)	0	-	-	-	-
Pericardial effusion	n (%)	2 (2.9)	0	-	-	-	-
Coronary artery disease	n (%)	0	1 (1.5)	-	-	-	-
Myocardial infarction	n (%)	0	1 (1.5)	-	-	-	-

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Cardiac disorders							
	Bundle branch block right	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Cardiac arrest	n (%)	1 (1.4)	0	-	-	-
					-	-	-
Metabolism and nutrition disorders							
		n (%)	6 (8.7)	2 (3.0)	-	-	-
					-	-	-
	Hyperlipidaemia	n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Metabolism and nutrition disorders							
Hyponatraemia	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Dehydration	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Diabetes mellitus	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Hypokalaemia	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Metabolism and nutrition disorders							
Hypomagnesaemia	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Malnutrition	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Vitamin D deficiency	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Musculoskeletal and connective tissue disorders	n (%)	2 (2.9)	4 (6.0)	-	-	-	-
				-	-	-	-

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Back pain	n (%)	1 (1.4)	1 (1.5)	-	-	-	-
				-	-	-	-
Bursitis	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Ligament sprain	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Plantar fasciitis	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Hand fracture	n (%)	1 (1.4)	0	-	-		-
				-	-		-
Pain in extremity	n (%)	1 (1.4)	0	-	-		-
				-	-		-
Nervous system disorders	n (%)	4 (5.8)	2 (3.0)	-	-		-
				-	-		-
Headache	n (%)	1 (1.4)	1 (1.5)	-	-		-
				-	-		-

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(Safety Population)

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MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Parkinson's disease	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Cerebral infarction	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Dementia	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Embolitic stroke	n (%)	1 (1.4)	0	-	-	-	-
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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Tremor	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Renal and urinary disorders	n (%)	3 (4.3)	2 (3.0)	-	-	-	-
				-	-	-	-
Haematuria	n (%)	2 (2.9)	1 (1.5)	-	-	-	-
				-	-	-	-
Urinary tract infection	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders							
Acute kidney injury	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Respiratory, thoracic and mediastinal disorders	n (%)	5 (7.2)	0	-	-	-	-
				-	-	-	-
Asthma	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Chronic obstructive pulmonary disease	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

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Respiratory, thoracic and mediastinal disorders							
Cough	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Pleural effusion	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Pneumonia	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Pulmonary fibrosis	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

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Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	1 (1.4)	3 (4.5)	-	-	-	-
Acute leukaemia	n (%)	0	1 (1.5)	-	-	-	-
Squamous cell carcinoma of skin	n (%)	0	1 (1.5)	-	-	-	-
Squamous cell carcinoma of the oral cavity	n (%)	0	1 (1.5)	-	-	-	-

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(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder cancer recurrent	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Skin and subcutaneous tissue disorders	n (%)	2 (2.9)	2 (3.0)	-	-	-	-
				-	-	-	-
Ecchymosis	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Tinea cruris	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-

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(Safety Population)

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MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Rash	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Skin lesion	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Gastrointestinal disorders	n (%)	3 (4.3)	1 (1.5)	-	-	-	-
				-	-	-	-
Nausea	n (%)	2 (2.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_81

DATE: 16JUL2024 11:17

Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Gastrointestinal disorders							
Small intestinal obstruction	n (%)	0	1 (1.5)	-	-	-	-
Gastrooesophageal reflux disease	n (%)	1 (1.4)	0	-	-	-	-
Melaena	n (%)	1 (1.4)	0	-	-	-	-
Immune system disorders	n (%)	1 (1.4)	2 (3.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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DATE: 16JUL2024 11:17

Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Immune system disorders							
Allergy to arthropod bite	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Iodine allergy	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Allergic sinusitis	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Psychiatric disorders	n (%)	1 (1.4)	2 (3.0)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Psychiatric disorders							
Anxiety	n (%)	0	2 (3.0)	-	-		-
				-	-		-
Stress	n (%)	1 (1.4)	0	-	-		-
				-	-		-
Blood and lymphatic system disorders	n (%)	1 (1.4)	1 (1.5)	-	-		-
				-	-		-
Anaemia	n (%)	0	1 (1.5)	-	-		-
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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DATE: 16JUL2024 11:17

Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Blood and lymphatic system disorders							
Blood loss anaemia	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
General disorders and administration site conditions	n (%)	2 (2.9)	0	-	-	-	-
				-	-	-	-
Cardiac death	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Peripheral swelling	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_81

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
 (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 TEAE	p-value [3]	0.5044
Eye disorders	p-value [3]	0.2316
Neovascular age-related macular degeneration	p-value [3]	0.2740
Visual acuity reduced	p-value [3]	0.1787
Conjunctival haemorrhage	p-value [3]	0.1551
Infections and infestations	p-value [3]	0.9573
Urinary tract infection	p-value [3]	0.7506
Investigations	p-value [3]	0.5279
Injury, poisoning and procedural complications	p-value [3]	0.1546
Vascular disorders	p-value [3]	0.8302

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
 [3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
 For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
 In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
 Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_81

DATE: 16JUL2024 11:17

Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
At Least 1 Serious TEAE	n (%)	7 (15.2)	8 (17.4)	1.1729 (0.3872, 3.5534)	1.1429 (0.4516, 2.8920)		0.0217 (-0.1292, 0.1726) 0.7789
Infections and infestations	n (%)	3 (6.5)	3 (6.5)	-	-		-
COVID-19	n (%)	1 (2.2)	1 (2.2)	-	-		-
Clostridium difficile infection	n (%)	0	1 (2.2)	-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_82

DATE: 16JUL2024 11:22

Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Infections and infestations							
Pneumonia	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
COVID-19 pneumonia	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Pyelonephritis	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Nervous system disorders	n (%)	3 (6.5)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:22

Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Cerebrovascular accident	n (%)	1 (2.2)	0	-	-	-	-
Confusional state	n (%)	1 (2.2)	0	-	-	-	-
Seizure	n (%)	1 (2.2)	0	-	-	-	-
Cardiac disorders	n (%)	0	2 (4.3)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_82

DATE: 16JUL2024 11:22

Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Cardiac disorders							
Acute myocardial infarction	n (%)	0	1 (2.2)	-	-	-	-
Aortic valve stenosis	n (%)	0	1 (2.2)	-	-	-	-
Bundle branch block	n (%)	0	1 (2.2)	-	-	-	-
Respiratory, thoracic and mediastinal disorders	n (%)	0	2 (4.3)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease	n (%)	0	1 (2.2)	-	-	-	-
Respiratory failure	n (%)	0	1 (2.2)	-	-	-	-
Vascular disorders	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
Transient ischaemic attack	n (%)	0	1 (2.2)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Vascular disorders							
Hypotension	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	2 (4.3)	0	-	-	-	-
Bladder neoplasm	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Squamous cell carcinoma of the tongue	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders	n (%)	2 (4.3)	0	-	-	-	-
Haemorrhage urinary tract	n (%)	1 (2.2)	0	-	-	-	-
Nephrolithiasis	n (%)	1 (2.2)	0	-	-	-	-
General disorders and administration site conditions	n (%)	0	1 (2.2)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
General disorders and administration site conditions							
Death	n (%)	0	1 (2.2)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Female						
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 Serious TEAE	n (%)	9 (13.0)	6 (9.0)	0.6557 (0.2199, 1.9557)	0.6866 (0.2585, 1.8234)	-0.0409 (-0.1457, 0.0639) 0.4484
Cardiac disorders	n (%)	3 (4.3)	1 (1.5)	-	-	-
Myocardial infarction	n (%)	0	1 (1.5)	-	-	-
Bundle branch block right	n (%)	1 (1.4)	0	-	-	-

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Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Cardiac disorders							
Cardiac arrest	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Pericardial effusion	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Injury, poisoning and procedural complications	n (%)	1 (1.4)	1 (1.5)	-	-	-	-
				-	-	-	-
Rib fracture	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications							
Hip fracture	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Metabolism and nutrition disorders	n (%)	1 (1.4)	1 (1.5)	-	-	-	-
				-	-	-	-
Hyponatraemia	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Hypokalaemia	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders	n (%)	2 (2.9)	0	-	-	-	-
				-	-	-	-
Cerebral infarction	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Embolic stroke	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Respiratory, thoracic and mediastinal disorders	n (%)	2 (2.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_82

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Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Asthma	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Pleural effusion	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Urinary tract infection	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_82

DATE: 16JUL2024 11:22

Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Musculoskeletal and connective tissue disorders	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Bursitis	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_82

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Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	0	1 (1.5)	-	-	-	-
Acute leukaemia	n (%)	0	1 (1.5)	-	-	-	-
General disorders and administration site conditions	n (%)	1 (1.4)	0	-	-	-	-
Cardiac death	n (%)	1 (1.4)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Vascular disorders	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Epistaxis	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_82

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Table Saf_82

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 Serious TEAE	p-value [3]	0.4651

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_82

DATE: 16JUL2024 11:22

Table Saf_83

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male						
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 Related TEAE	n (%)	4 (8.7)	11 (23.9)	3.3000 (0.9654,11.2805)	2.7500 (0.9443, 8.0086)	0.1522 (0.0044,0.2999) 0.0494
Eye disorders	n (%)	3 (6.5)	11 (23.9)	4.5048 (1.1651,17.4174)	3.6667 (1.0940,12.2889)	0.1739 (0.0315,0.3163) 0.0209
Conjunctival haemorrhage	n (%)	1 (2.2)	2 (4.3)	-	-	-
Corneal abrasion	n (%)	1 (2.2)	2 (4.3)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_83

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Table Saf_83

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Vitreous floaters	n (%)	0	2 (4.3)	-	-	-	-
				-	-	-	-
Vitreous haemorrhage	n (%)	0	2 (4.3)	-	-	-	-
				-	-	-	-
Dry eye	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
				-	-	-	-
Eye irritation	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_83

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Photopsia	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Retinal pigment epithelial tear	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Conjunctival hyperaemia	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Eye pain	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_83

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Lacrimation increased	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Punctate keratitis	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Cardiac disorders	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Acute myocardial infarction	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_83

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Table Saf_83

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Male						
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) [1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	n (%)	0	1 (2.2)	-	-	-
				-	-	-
Blood pressure increased	n (%)	0	1 (2.2)	-	-	-
				-	-	-
Injury, poisoning and procedural complications	n (%)	1 (2.2)	0	-	-	-
				-	-	-
Procedural pain	n (%)	1 (2.2)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_83

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Table Saf_83

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) [1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value [2]
At Least 1 Related TEAE	n (%)	5 (7.2)	9 (13.4)	1.9862 (0.6292, 6.2698)	1.8537 (0.6550, 5.2459)		0.0619 (-0.0402, 0.1639) 0.2370
Eye disorders	n (%)	3 (4.3)	7 (10.4)	2.5667 (0.6349, 10.3767)	2.4030 (0.6483, 8.9064)		0.0610 (-0.0266, 0.1486) 0.1746
Conjunctival haemorrhage	n (%)	1 (1.4)	7 (10.4)	-	-		-
Dry eye	n (%)	0	1 (1.5)	-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_83

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Table Saf_83

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) [1]	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value [2]
Eye disorders							
Eye irritation	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Iritis	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Punctate keratitis	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Vitreous floaters	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_83

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) [1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value [2]
Eye disorders							
Dry age-related macular degeneration	n (%)	1 (1.4)	0	-	-	-	-
Subretinal fluid	n (%)	1 (1.4)	0	-	-	-	-
Investigations	n (%)	0	2 (3.0)	-	-	-	-
Intraocular pressure increased	n (%)	0	2 (3.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_83

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Table Saf_83

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) [1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Immune system disorders	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Iodine allergy	n (%)	0	1 (1.5)	-	-	-	-
				-	-	-	-
Injury, poisoning and procedural complications	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Procedural pain	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_83

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Table Saf_83

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-
Cerebral infarction	n (%)	1 (1.4)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_83

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 Related TEAE	p-value [3]	0.5857
Eye disorders	p-value [3]	0.4153

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_83

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Table Saf_84

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Male						
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) [1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious Related TEAE	n (%)	0	1 (2.2)	-	-	-
Cardiac disorders	n (%)	0	1 (2.2)	-	-	-
Acute myocardial infarction	n (%)	0	1 (2.2)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_84

DATE: 11JUL2024 6:18

Table Saf_84

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Female						
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious Related TEAE	n (%)	1 (1.4)	1 (1.5)	-	-	-
Investigations	n (%)	0	1 (1.5)	-	-	-
Intraocular pressure increased	n (%)	0	1 (1.5)	-	-	-
Nervous system disorders	n (%)	1 (1.4)	0	-	-	-
Cerebral infarction	n (%)	1 (1.4)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male									
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]		
At Least 1 TEAE		n (%)	36 (78.3)	33 (71.7)	0.7051 (0.2727, 1.8235)	0.9167 (0.7234, 1.1616)	-0.0652 (-0.2417, 0.1112) 0.4725		
Eye disorders	Grade 1	n (%)	15 (32.6)	17 (37.0)	1.2115 (0.5130, 2.8610)	1.1333 (0.6465, 1.9867)	0.0435 (-0.1510, 0.2379) 0.6633		
	Grade 2	n (%)	8 (17.4)	7 (15.2)	0.8526 (0.2814, 2.5829)	0.8750 (0.3458, 2.2142)	-0.0217 (-0.1726, 0.1292) 0.7789		
	Grade 3	n (%)	1 (2.2)	0	-	-	-		
	Grade 4	n (%)	0	0	-	-	-		
	Grade 5	n (%)	0	0	-	-	-		

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male									
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]		
Eye disorders									
Neovascular age-related macular degeneration	Grade 1	n (%)	3 (6.5)	3 (6.5)	1.0000 (0.1911, 5.2341)	1.0000 (0.2128, 4.6985)	0.0000 (-0.1009, 0.1009) >0.9999		
	Grade 2	n (%)	1 (2.2)	2 (4.3)	- -	- -	- -		
	Grade 3	n (%)	0	0	- -	- -	- -		
	Grade 4	n (%)	0	0	- -	- -	- -		
	Grade 5	n (%)	0	0	- -	- -	- -		

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	2 (4.3)	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	4 (8.7)	1 (2.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Vitreous floaters	Grade 1	n (%)	1 (2.2)	4 (8.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Subretinal fluid	Grade 1	n (%)	1 (2.2)	2 (4.3)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	1 (2.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Corneal abrasion	Grade 1	n (%)	0	2 (4.3)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	1 (2.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Cataract	Grade 1	n (%)	1 (2.2)	2 (4.3)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Dry eye	Grade 1	n (%)	1 (2.2)	2 (4.3)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Eye pain	Grade 1	n (%)	2 (4.3)	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	1 (2.2)	2 (4.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Dermatochalasis	Grade 1	n (%)	2 (4.3)	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal haemorrhage	Grade 1	n (%)	1 (2.2)	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Cataract	Grade 1	n (%)	0	2 (4.3)	-	-	-
nuclear					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Photopsia	Grade 1	n (%)	0	2 (4.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous haemorrhage	Grade 1	n (%)	0	2 (4.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cystoid macular oedema	Grade 1	n (%)	1 (2.2)	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Hordeolum	Grade 1	n (%)	1 (2.2)	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Punctate keratitis	Grade 1	n (%)	1 (2.2)	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Posterior capsule opacification	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal oedema	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Vision blurred	Grade 1	n (%)	2 (4.3)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Angle closure glaucoma	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Chorioretinopathy	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Choroidal neovascularisation	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Conjunctivitis allergic	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eye irritation	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Iridocyclitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Macular scar	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Retinal pigment epithelial tear	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal pigmentation	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Trichiasis	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Conjunctival hyperaemia	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Detachment of retinal pigment epithelium	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Dry age-related macular degeneration	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Entropion	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Exposure keratitis	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Eyelid ptosis	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Macular oedema	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Metamorphopsia	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Retinal degeneration	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Retinal detachment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal drusen	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Retinal tear	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Retinal vein occlusion	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Subretinal fibrosis	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Vitreous detachment	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
MedDRA Preferred Term	Grade	n (%)						
Investigations	Grade 1	n (%)	7 (15.2)	9 (19.6)	1.3552 (0.4578, 4.0120)	1.2857 (0.5231, 3.1599)	0.0435 (-0.1112, 0.1981) 0.5843	
	Grade 2	n (%)	1 (2.2)	0	-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
	Grade 5	n (%)	0	0	-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	Difference 95% CI p-value[2]
Investigations							
Blood pressure increased	Grade 1	n (%)	1 (2.2)	2 (4.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	1 (2.2)	2 (4.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Urine analysis abnormal	Grade 1	n (%)	0	2 (4.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Bacterial test positive	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Blood pressure diastolic decreased	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure diastolic increased	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Protein urine present	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Weight decreased	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	Difference 95% CI p-value[2]
Investigations							
Basophil count increased	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	1 (2.2)	0	-	-	-
creatinine							
abnormal	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	Difference 95% CI p-value[2]
Investigations							
Blood urea abnormal	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Eosinophil count increased	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Haematocrit decreased	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Haemoglobin decreased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Neutrophil count increased	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Platelet count decreased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	Difference 95% CI p-value[2]
Investigations							
Red blood cell count decreased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cell count increased	Grade 1	n (%)	1 (2.2)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations	Grade 1	n (%)	1 (2.2)	1 (2.2)	1.0000 (0.0607, 16.4848)	1.0000 (0.0645, 15.5104)	0.0000 (-0.0596, 0.0596) >0.9999
	Grade 2	n (%)	2 (4.3)	3 (6.5)	-	-	-
	Grade 3	n (%)	2 (4.3)	2 (4.3)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	1 (2.2)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	1 (2.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (2.2)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Clostridium difficile infection	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Conjunctivitis	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Influenza	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Anogenital warts	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19 pneumonia	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	1 (2.2)	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Cellulitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Pyelonephritis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Sepsis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Sinusitis	Grade 1	n (%)	1 (2.2)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	3 (6.5)	2 (4.3)	-	-	-
					-	-	-
	Grade 2	n (%)	2 (4.3)	1 (2.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Fall	Grade 1	n (%)	2 (4.3)	1 (2.2)	- -	- -	- -
	Grade 2	n (%)	1 (2.2)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Contusion	Grade 1	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Skin abrasion	Grade 1	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Skin laceration	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Joint injury	Grade 1	n (%)	1 (2.2)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Procedural pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Traumatic haematoma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	3 (6.5)	2 (4.3)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	2 (4.3)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Basal cell carcinoma	Grade 1	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Keratoacanthoma	Grade 1	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of skin	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acrochordon	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder cancer	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder neoplasm	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Eye naevus	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Skin cancer	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of the tongue	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders	Grade 1	n (%)	2 (4.3)	2 (4.3)	-	-	-
					-	-	-
	Grade 2	n (%)	4 (8.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Dizziness	Grade 1	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Migraine	Grade 1	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade							
Nervous system disorders								
Cerebral small vessel ischaemic disease	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebrovascular accident	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Confusional state	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Facial paralysis	Grade 1	n (%)	1 (2.2)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Headache	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Metabolic encephalopathy	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	1 (2.2)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Sciatica	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Seizure	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders	Grade 1	n (%)	2 (4.3)	3 (6.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Vitamin D deficiency	Grade 1	n (%)	0	2 (4.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Dyslipidaemia	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hyperlipidaemia	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Glucose tolerance impaired	Grade 1	n (%)	1 (2.2)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hyperkalaemia	Grade 1	n (%)	1 (2.2)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Renal and urinary disorders	Grade 1	n (%)	0	2 (4.3)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	2 (4.3)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Cystitis	Grade 1	n (%)	0	2 (4.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Dysuria	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Bladder diverticulum	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Renal and urinary disorders							
Haematuria	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Haemorrhage urinary tract	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Renal and urinary disorders							
Nephrolithiasis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Renal cyst	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Renal tubular necrosis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Urinary bladder haemorrhage	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Urinary retention	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)						
Vascular disorders	Grade 1	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	2 (4.3)	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypotension	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Transient ischaemic attack	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (2.2)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Dizziness	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Vascular disorders							
Hypertension	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Pulmonary congestion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Venous occlusion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Cardiac disorders	Grade 1	n (%)	0	1 (2.2)	-	-	-	-
	Grade 2	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
	Grade 3	n (%)	0	2 (4.3)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Acute myocardial infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	Difference 95% CI p-value[2]
Cardiac disorders							
Aortic valve stenosis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Arrhythmia	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Bradycardia	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Bundle branch block	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk Difference	
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	95% CI	p-value[2]
Cardiac disorders								
Atrial fibrillation	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
General disorders and administration site conditions	Grade 1	n (%)	1 (2.2)	0	-	-	-	-
	Grade 2	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	1 (2.2)	-	-	-	-
					-	-	-	-
					-	-	-	-
					-	-	-	-
					-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Asthenia	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Death	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (2.2)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Gait inability	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
Grade 4	n (%)	0	0		-	-	-
					-	-	-
Grade 5	n (%)	0	0		-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Pyrexia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Respiratory, thoracic and mediastinal disorders	Grade 1	n (%)	1 (2.2)	0	-	-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-	-
	Grade 3	n (%)	0	2 (4.3)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Cough	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Epistaxis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Respiratory failure	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Atelectasis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Hypoxia	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Nasal congestion	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Oropharyngeal pain	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:28

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pleural effusion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pulmonary oedema	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	0	2 (4.3)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders Eczema							
	Grade 1	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders Skin lesion							
	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)						
Blood and lymphatic system disorders	Grade 1	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Microcytic anaemia	Grade 1	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Lymphadenopathy	Grade 1	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Joint swelling	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Reproductive system and breast disorders	Grade 1	n (%)	1 (2.2)	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Reproductive system and breast disorders							
Prostatomegaly	Grade 1	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Reproductive system and breast disorders							
Benign prostatic hyperplasia	Grade 1	n (%)	1 (2.2)	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)						
Immune system disorders	Grade 1	n (%)	0	1 (2.2)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Seasonal allergy	Grade 1	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female									
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]		
At Least 1 TEAE		n (%)	49 (71.0)	49 (73.1)	1.1111 (0.5249, 2.3519)	1.0299 (0.8354, 1.2696)	0.0212 (-0.1295, 0.1719) 0.7838		
Eye disorders	Grade 1	n (%)	26 (37.7)	22 (32.8)	0.8085 (0.3995, 1.6364)	0.8714 (0.5515, 1.3770)	-0.0485 (-0.2088, 0.1119) 0.5559		
	Grade 2	n (%)	10 (14.5)	3 (4.5)	0.2766 (0.0726, 1.0539)	0.3090 (0.0889, 1.0737)	-0.1002 (-0.1969, -0.0034) 0.0479		
	Grade 3	n (%)	0	1 (1.5)	-	-	-		
	Grade 4	n (%)	0	0	-	-	-		
	Grade 5	n (%)	0	0	-	-	-		

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Eye disorders								
Neovascular age-related macular degeneration	Grade 1	n (%)	7 (10.1)	3 (4.5)	0.4152 (0.1027, 1.6784)	0.4414 (0.1191, 1.6359)	-0.0567 (-0.1434, 0.0301) 0.2072	
	Grade 2	n (%)	1 (1.4)	1 (1.5)	- -	- -	- -	
	Grade 3	n (%)	0	0	- -	- -	- -	
	Grade 4	n (%)	0	0	- -	- -	- -	
	Grade 5	n (%)	0	0	- -	- -	- -	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	7 (10.1)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	4 (5.8)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	1 (1.4)	8 (11.9)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Retinal haemorrhage	Grade 1	n (%)	5 (7.2)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous detachment	Grade 1	n (%)	1 (1.4)	3 (4.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Dry eye	Grade 1	n (%)	3 (4.3)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Metamorphopsia	Grade 1	n (%)	3 (4.3)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Subretinal fluid	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	2 (2.9)	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Punctate keratitis	Grade 1	n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Subretinal fibrosis	Grade 1	n (%)	1 (1.4)	2 (3.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Corneal abrasion	Grade 1	n (%)	0	2 (3.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Vision blurred	Grade 1	n (%)	0	2 (3.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Cataract	Grade 1	n (%)	1 (1.4)	1 (1.5)	-	-	-
cortical					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Posterior capsule opacification	Grade 1	n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Retinal degeneration	Grade 1	n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:28

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Dry age-related macular degeneration	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk Difference
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	95% CI p-value[2]
Eye disorders							
Retinal oedema	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cataract nuclear	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Dacryostenosis acquired	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Dermatochalasis	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eye irritation	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Eye pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Eye swelling	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Iritis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Macular hole	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Retinal tear	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous floaters	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Vitreous opacities	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Blepharitis	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Blindness	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival hyperaemia	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Cystoid macular oedema	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Detachment of retinal pigment epithelium	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Foveal degeneration	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Hordeolum	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Macular fibrosis	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Macular pigmentation	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Macular scar	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Meibomian gland dysfunction	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Retinal pigmentation	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal vein occlusion	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Vitreous haemorrhage	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations	Grade 1	n (%)	7 (10.1)	7 (10.4)	1.0333 (0.3419, 3.1234)	1.0299 (0.3818, 2.7778)	0.0030 (-0.0991, 0.1052) 0.9538
	Grade 2	n (%)	2 (2.9)	3 (4.5)	-	-	-
	Grade 3	n (%)	0	1 (1.5)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	4 (5.8)	3 (4.5)	- -	- -	- -
	Grade 2	n (%)	1 (1.4)	3 (4.5)	- -	- -	- -
	Grade 3	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Bronchitis	Grade 1	n (%)	2 (2.9)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19	Grade 1	n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Sinusitis	Grade 1	n (%)	0	2 (3.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Acute sinusitis	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Fungal infection	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Upper respiratory tract infection	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Herpes zoster	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade	n (%)					
Investigations	Grade 1	n (%)	5 (7.2)	7 (10.4)	1.4933 (0.4496, 4.9604)	1.4418 (0.4812, 4.3197)	0.0320 (-0.0634, 0.1274) 0.5121
	Grade 2	n (%)	0	2 (3.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	0	4 (6.0)	- -	- -	- -
	Grade 2	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Investigations							
Blood pressure diastolic decreased	Grade 1	n (%)	0	2 (3.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure increased	Grade 1	n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Urine analysis abnormal	Grade 1	n (%)	2 (2.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Bacterial test positive	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	0	1 (1.5)	-	-	-
creatinine					-	-	-
increased	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	0	1 (1.5)	-	-	-
triglycerides					-	-	-
increased	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Haematocrit decreased	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Haemoglobin decreased	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Laboratory test	Grade 1	n (%)	0	0	-	-	-
abnormal							
	Grade 2	n (%)	0	1 (1.5)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Investigations							
Lymphocyte count decreased	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Monocyte count increased	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Neutrophil count increased	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Urine leukocyte esterase positive	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cell count increased	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Investigations							
Blood uric acid increased	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cells urine positive	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	2 (2.9)	4 (6.0)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	3 (4.5)	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Fall	Grade 1	n (%)	1 (1.4)	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Head injury	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	2 (3.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Procedural pain	Grade 1	n (%)	1 (1.4)	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Rib fracture	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	1 (1.4)	0	- -	- -	- -
	Grade 3	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Face injury	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Facial bones fracture	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Tooth fracture	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Hip fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade	n (%)					
Vascular disorders	Grade 1	n (%)	4 (5.8)	4 (6.0)	-	-	-
					-	-	-
	Grade 2	n (%)	2 (2.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Vascular disorders							
Essential hypertension	Grade 1	n (%)	0	2 (3.0)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Syncope	Grade 1	n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypertension	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Vascular disorders							
Aortic arteriosclerosis	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Dizziness	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Epistaxis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hot flush	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypotension	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Cardiac disorders	Grade 1	n (%)	0	1 (1.5)	-	-	-	-
	Grade 2	n (%)	1 (1.4)	2 (3.0)	-	-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-	-
	Grade 4	n (%)	1 (1.4)	0	-	-	-	-
	Grade 5	n (%)	1 (1.4)	1 (1.5)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Atrial fibrillation	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (1.4)	2 (3.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Cardiac failure congestive	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Cardiac disorders							
Pericardial effusion	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Coronary artery disease	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	Difference 95% CI p-value[2]
Cardiac disorders							
Myocardial infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (1.5)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk Difference
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=69)	(N=67)	95% CI	95% CI	95% CI p-value[2]
Cardiac disorders							
Bundle branch block right	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Cardiac arrest	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	1 (1.4)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade							
Metabolism and nutrition disorders	Grade 1	n (%)	4 (5.8)	1 (1.5)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	2 (2.9)	1 (1.5)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hyperlipidaemia	Grade 1	n (%)	1 (1.4)	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hyponatraemia	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Dehydration	Grade 1	n (%)	1 (1.4)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Diabetes mellitus	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypokalaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypomagnesaemia	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Malnutrition	Grade 1	n (%)	1 (1.4)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Vitamin D deficiency	Grade 1	n (%)	1 (1.4)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Female								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)						
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	2 (3.0)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	2 (2.9)	1 (1.5)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	1 (1.5)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Musculoskeletal and connective tissue disorders							
Bursitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Musculoskeletal and connective tissue disorders							
Ligament sprain	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Plantar fasciitis	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Hand fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Musculoskeletal and connective tissue disorders							
Pain in extremity	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade	n (%)					
Nervous system disorders	Grade 1	n (%)	2 (2.9)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Headache	Grade 1	n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Parkinson's disease	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebral infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Dementia	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Nervous system disorders							
Embololic stroke	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Nervous system disorders							
Tremor	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders	Grade 1	n (%)	3 (4.3)	1 (1.5)	-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Haematuria	Grade 1	n (%)	2 (2.9)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Urinary tract infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Renal and urinary disorders							
Acute kidney injury	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Respiratory, thoracic and mediastinal disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	3 (4.3)	0	-	-	-	-
	Grade 3	n (%)	2 (2.9)	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Asthma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders Cough	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pleural effusion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pulmonary fibrosis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 2	n (%)	1 (1.4)	1 (1.5)	-	-	-	
					-	-	-	
	Grade 3	n (%)	0	2 (3.0)	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	0	0	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acute leukaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of skin	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of the oral cavity	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (1.5)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder cancer recurrent	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	2 (2.9)	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders Ecchymosis							
	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Skin and subcutaneous tissue disorders							
Tinea cruris	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Skin and subcutaneous tissue disorders							
Rash	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Skin lesion	Grade 1	n (%)	1 (1.4)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders	Grade 1	n (%)	3 (4.3)	1 (1.5)	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Nausea	Grade 1	n (%)	2 (2.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Small intestinal obstruction	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Gastroesophageal reflux disease	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders	Grade						
Melaena	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade	n (%)	1 (1.4)	2 (3.0)			
Immune system disorders	Grade 1	n (%)	1 (1.4)	2 (3.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Allergy to arthropod bite	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Immune system disorders							
Iodine allergy	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Immune system disorders							
Allergic sinusitis	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Anxiety	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Stress	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)						
Blood and lymphatic system disorders	Grade 1	n (%)	1 (1.4)	1 (1.5)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Anaemia	Grade 1	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Blood loss anaemia	Grade 1	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
General disorders and administration site conditions	Grade 1	n (%)	1 (1.4)	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	1 (1.4)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Cardiac death	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	1 (1.4)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Peripheral swelling	Grade 1	n (%)	1 (1.4)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Date of data extract: 26AUG2020

Table Saf_85

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic p-value [3]	Interaction
At Least 1 TEAE			0.5044
Eye disorders	Grade 1	p-value [3]	0.4624
Neovascular age-related macular degeneration	Grade 2	p-value [3]	0.2487
	Grade 1	p-value [3]	0.3216
Infections and infestations	Grade 1	p-value [3]	0.9710
Investigations	Grade 1	p-value [3]	0.9605

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_85

DATE: 16JUL2024 11:28

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) [1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value [2]	
At Least 1 Serious TEAE		n (%)	7 (15.2)	8 (17.4)	1.1729 (0.3872, 3.5534)	1.1429 (0.4516, 2.8920)	0.0217 (-0.1292, 0.1726) 0.7789	
Infections and infestations	Grade 1	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 2	n (%)	1 (2.2)	0	-	-	-	
					-	-	-	
	Grade 3	n (%)	2 (4.3)	2 (4.3)	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	0	1 (2.2)	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	1 (2.2)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	1 (2.2)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Clostridium difficile infection	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	1 (2.2)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19 pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Pyelonephritis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Nervous system disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	3 (6.5)	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
Grade 4	n (%)	0	0	0	-	-	-	-
					-	-	-	-
Grade 5	n (%)	0	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebrovascular accident	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Confusional state	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	1 (2.2)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Seizure	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Cardiac disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	2 (4.3)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Acute myocardial infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Aortic valve stenosis	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (2.2)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=46)	(N=46)	95% CI	95% CI	Difference 95% CI p-value[2]
Cardiac disorders							
Bundle branch block	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Respiratory, thoracic and mediastinal disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	2 (4.3)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Respiratory failure	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (2.2)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Vascular disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (2.2)	1 (2.2)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Transient ischaemic attack	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (2.2)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypotension	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder neoplasm	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of the tongue	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Renal and urinary disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	2 (4.3)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Haemorrhage urinary tract	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Renal and urinary disorders							
Nephrolithiasis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (2.2)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Protocol ONS-5010-002

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
General disorders and administration site conditions	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	1 (2.2)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Death	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (2.2)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
At Least 1 Serious TEAE	Grade	n (%)	9 (13.0)	6 (9.0)	0.6557 (0.2199, 1.9557)	0.6866 (0.2585, 1.8234)	-0.0409 (-0.1457, 0.0639)	0.4484
Cardiac disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	1 (1.4)	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	1 (1.4)	1 (1.5)	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Cardiac disorders							
Myocardial infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (1.5)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Bundle branch block right	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Cardiac arrest	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	1 (1.4)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Pericardial effusion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (1.4)	1 (1.5)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Rib fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Hip fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Metabolism and nutrition disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (1.4)	1 (1.5)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hyponatraemia	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypokalaemia	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	1 (1.4)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Nervous system disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	1 (1.4)	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebral infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Embololic stroke	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Respiratory, thoracic and mediastinal disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Asthma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pleural effusion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Infections and infestations	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	1 (1.5)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Investigations	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	1 (1.5)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Bursitis	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	1 (1.5)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	1 (1.5)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acute leukaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (1.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Protocol ONS-5010-002

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
General disorders and administration site conditions	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	1 (1.4)	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Date of data extract: 26AUG2020

Table Saf_86

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Cardiac death	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	1 (1.4)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Vascular disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Epistaxis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (1.4)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_86

DATE: 16JUL2024 11:32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-2 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Interaction
MedDRA Preferred Term		p-value [3]	
At Least 1 Serious TEAE			0.4651

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.7.1, 16.2.7.2

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Table Saf_87

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	2 (4.3)	2 (4.3)	-	-	-	-
				-	-	-	-
General disorders and administration site conditions	n (%)	0	2 (4.3)	-	-	-	-
Asthenia	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Death	n (%)	0	1 (2.2)	-	-	-	-
				-	-	-	-
Eye disorders	n (%)	2 (4.3)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_87

DATE: 11JUL2024 5:26

Table Saf_87

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data) (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Eye disorders							
Retinal oedema	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Subretinal fluid	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-
Visual acuity reduced	n (%)	1 (2.2)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_87

DATE: 11JUL2024 5:26

Table Saf_87

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	3 (4.3)	0	-	-	-	-
Cardiac disorders	n (%)	1 (1.4)	0	-	-	-	-
Cardiac arrest	n (%)	1 (1.4)	0	-	-	-	-
Nervous system disorders	n (%)	1 (1.4)	0	-	-	-	-
Cerebral infarction	n (%)	1 (1.4)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_87

DATE: 11JUL2024 5:26

Table Saf_87

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Gender in NORSE-2 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data) (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value
Respiratory, thoracic and mediastinal disorders	n (%)	1 (1.4)	0	-	-	-	-
Pulmonary fibrosis	n (%)	1 (1.4)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_87

DATE: 11JUL2024 5:26

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
At Least 1 TEAE	n (%)	4 (80.0)	3 (75.0)	0.7500 (0.0321, 17.5056)	0.9375 (0.4583, 1.9177)		-0.0500 (-0.6004, 0.5004) 0.8658
Eye disorders	n (%)	4 (80.0)	2 (50.0)	0.2500 (0.0132, 4.7287)	0.6250 (0.2136, 1.8285)		-0.3000 (-0.9025, 0.3025) 0.3711
Corneal abrasion	n (%)	0	1 (25.0)	-	-		-
Cystoid macular oedema	n (%)	0	1 (25.0)	-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Trichiasis	n (%)	0	1 (25.0)	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	1 (20.0)	0	-	-	-	-
				-	-	-	-
Retinal pigmentation	n (%)	1 (20.0)	0	-	-	-	-
				-	-	-	-
Subretinal fluid	n (%)	1 (20.0)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Vision blurred	n (%)	1 (20.0)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	1 (20.0)	1 (25.0)	1.3333 (0.0571, 31.1210)	1.2500 (0.1089, 14.3432)	0.0500 (-0.5004, 0.6004)	0.8658
Conjunctivitis	n (%)	0	1 (25.0)	-	-	-	-
				-	-	-	-
Bronchitis	n (%)	1 (20.0)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations	n (%)	0	1 (25.0)	4.7143 (0.1467, 151.4799)	3.6000 (0.1842, 70.3418)		0.2167 (-0.2419, 0.6752) 0.3764
Intraocular pressure increased	n (%)	0	1 (25.0)	- -	- -		- - -
Cardiac disorders	n (%)	1 (20.0)	0	0.3333 (0.0105, 10.5744)	0.4000 (0.0205, 7.8158)		-0.1500 (-0.5850, 0.2850) 0.5403
Cardiac arrest	n (%)	1 (20.0)	0	- -	- -		- - -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Gastrointestinal disorders	n (%)	1 (20.0)	0	-	-	-	-
Nausea	n (%)	1 (20.0)	0	-	-	-	-
Nervous system disorders	n (%)	1 (20.0)	0	0.3333 (0.0105, 10.5744)	0.4000 (0.0205, 7.8158)	-0.1500 (-0.5850, 0.2850)	0.5403
Headache	n (%)	1 (20.0)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders	n (%)	1 (20.0)	0	-	-	-	-
Asthma	n (%)	1 (20.0)	0	-	-	-	-
Vascular disorders	n (%)	1 (20.0)	0	0.3333 (0.0105, 10.5744)	0.4000 (0.0205, 7.8158)	-0.1500 (-0.5850, 0.2850)	0.5403
Hot flush	n (%)	1 (20.0)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
At Least 1 TEAE	n (%)	81 (73.6)	79 (72.5)	0.9428 (0.5189, 1.7130)	0.9843 (0.8380, 1.1561)		-0.0116 (-0.1291, 0.1059) 0.8470
Eye disorders	n (%)	56 (50.9)	48 (44.0)	0.7588 (0.4458, 1.2914)	0.8650 (0.6537, 1.1446)		-0.0687 (-0.2007, 0.0632) 0.3096
Neovascular age-related macular degeneration	n (%)	12 (10.9)	9 (8.3)	0.7350 (0.2964, 1.8224)	0.7569 (0.3325, 1.7231)		-0.0265 (-0.1044, 0.0513) 0.5061

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
	Visual acuity reduced	n (%)	17 (15.5)	3 (2.8)	0.1548 (0.0440, 0.5451)	0.1781 (0.0537, 0.5904)	-0.1270 (-0.2012, -0.0528) 0.0011
	Conjunctival haemorrhage	n (%)	3 (2.7)	10 (9.2)	3.6027 (0.9635, 13.4708)	3.3639 (0.9516, 11.8915)	0.0645 (0.0023, 0.1266) 0.0440
	Retinal haemorrhage	n (%)	8 (7.3)	3 (2.8)	0.3608 (0.0931, 1.3982)	0.3784 (0.1031, 1.3889)	-0.0452 (-0.1026, 0.0122) 0.1265

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Subretinal fluid	n (%)	4 (3.6)	4 (3.7)	-	-	-	-
				-	-	-	-
Dry eye	n (%)	5 (4.5)	3 (2.8)	-	-	-	-
				-	-	-	-
Vitreous floaters	n (%)	1 (0.9)	5 (4.6)	-	-	-	-
				-	-	-	-

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Corneal abrasion	n (%)	1 (0.9)	4 (3.7)	-	-	-	-
				-	-	-	-
Eye pain	n (%)	2 (1.8)	3 (2.8)	-	-	-	-
				-	-	-	-
Punctate keratitis	n (%)	2 (1.8)	3 (2.8)	-	-	-	-
				-	-	-	-

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Vitreous detachment	n (%)	2 (1.8)	3 (2.8)	-	-	-	-
				-	-	-	-
Metamorphopsia	n (%)	4 (3.6)	1 (0.9)	-	-	-	-
				-	-	-	-
Cataract	n (%)	2 (1.8)	2 (1.8)	-	-	-	-
				-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Dermatochalasis	n (%)	2 (1.8)	2 (1.8)	-	-	-	-
				-	-	-	-
Subretinal fibrosis	n (%)	2 (1.8)	2 (1.8)	-	-	-	-
				-	-	-	-
Posterior capsule opacification	n (%)	3 (2.7)	1 (0.9)	-	-	-	-
				-	-	-	-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Retinal oedema	n (%)	4 (3.6)	0	-	-	-	-
				-	-	-	-
Cataract nuclear	n (%)	0	3 (2.8)	-	-	-	-
				-	-	-	-
Vision blurred	n (%)	1 (0.9)	2 (1.8)	-	-	-	-
				-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Vitreous haemorrhage	n (%)	1 (0.9)	2 (1.8)	-	-	-	-
				-	-	-	-
Hordeolum	n (%)	2 (1.8)	1 (0.9)	-	-	-	-
				-	-	-	-
Retinal degeneration	n (%)	2 (1.8)	1 (0.9)	-	-	-	-
				-	-	-	-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Dry age-related macular degeneration	n (%)	3 (2.7)	0	-	-	-	-
Eye irritation	n (%)	0	2 (1.8)	-	-	-	-
Photopsia	n (%)	0	2 (1.8)	-	-	-	-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Cataract cortical	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
				-	-	-	-
Macular scar	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
				-	-	-	-
Retinal tear	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Zero count correction was applied according to the method proposed by IQWiG.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Conjunctival hyperaemia	n (%)	2 (1.8)	0		-	-	-
					-	-	-
Cystoid macular oedema	n (%)	2 (1.8)	0		-	-	-
					-	-	-
Detachment of retinal pigment epithelium	n (%)	2 (1.8)	0		-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Retinal vein occlusion	n (%)	2 (1.8)	0	-	-	-	-
				-	-	-	-
Angle closure glaucoma	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Chorioretinopathy	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Choroidal neovascularisation	n (%)	0	1 (0.9)	-	-	-	-
Conjunctivitis allergic	n (%)	0	1 (0.9)	-	-	-	-
Dacryostenosis acquired	n (%)	0	1 (0.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Eye swelling	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Iridocyclitis	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Iritis	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Macular hole	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Retinal pigment epithelial tear	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Retinal pigmentation	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Vitreous opacities	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Blepharitis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Blindness	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Entropion	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Exposure keratitis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Eyelid ptosis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Foveal degeneration	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Macular fibrosis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Macular oedema	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Macular pigmentation	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Meibomian gland dysfunction	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Retinal detachment	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Retinal drusen	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	13 (11.8)	17 (15.6)	1.3788 (0.6343, 2.9970)	1.3197 (0.6741, 2.5836)	0.0378 (-0.0532, 0.1288)	0.4173

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Infections and infestations							
Urinary tract infection	n (%)	5 (4.5)	8 (7.3)	1.6634 (0.5265, 5.2546)	1.6147 (0.5453, 4.7809)		0.0279 (-0.0346, 0.0905) 0.3827
COVID-19	n (%)	4 (3.6)	3 (2.8)	-	-		-
				-	-		-
Sinusitis	n (%)	1 (0.9)	2 (1.8)	-	-		-
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Infections and infestations							
Bronchitis	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
				-	-	-	-
Pneumonia	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
				-	-	-	-
Acute sinusitis	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Infections and infestations							
Clostridium difficile infection		n (%)	0	1 (0.9)	-	-	-
					-	-	-
Fungal infection		n (%)	0	1 (0.9)	-	-	-
					-	-	-
Influenza		n (%)	0	1 (0.9)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Infections and infestations							
Upper respiratory tract infection		n (%)	0	1 (0.9)	-	-	-
Anogenital warts		n (%)	1 (0.9)	0	-	-	-
COVID-19 pneumonia		n (%)	1 (0.9)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Infections and infestations							
Cellulitis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Herpes zoster	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Pyelonephritis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Infections and infestations	Sepsis	n (%)	1 (0.9)	0	-	-	-
					-	-	-
Investigations		n (%)	13 (11.8)	17 (15.6)	1.3788 (0.6343, 2.9970)	1.3197 (0.6741, 2.5836)	0.0378 (-0.0532, 0.1288)
Intraocular pressure increased		n (%)	1 (0.9)	6 (5.5)	-	-	0.4173
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood pressure increased	n (%)	2 (1.8)	3 (2.8)	-	-	-	-
				-	-	-	-
Urine analysis abnormal	n (%)	2 (1.8)	2 (1.8)	-	-	-	-
				-	-	-	-
Blood pressure diastolic decreased	n (%)	0	3 (2.8)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Bacterial test positive	n (%)	0	2 (1.8)	-	-	-	-
				-	-	-	-
Haematocrit decreased	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
				-	-	-	-
Haemoglobin decreased	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Neutrophil count increased	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
White blood cell count increased	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
Blood creatinine increased	n (%)	0	1 (0.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood pressure diastolic increased	n (%)	0	1 (0.9)	-	-	-	-
Blood triglycerides increased	n (%)	0	1 (0.9)	-	-	-	-
Laboratory test abnormal	n (%)	0	1 (0.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Lymphocyte count decreased	n (%)	0	1 (0.9)	-	-	-	-
Monocyte count increased	n (%)	0	1 (0.9)	-	-	-	-
Protein urine present	n (%)	0	1 (0.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Urine leukocyte esterase positive	n (%)	0	1 (0.9)	-	-	-	-
Weight decreased	n (%)	0	1 (0.9)	-	-	-	-
Basophil count increased	n (%)	1 (0.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood creatinine abnormal	n (%)	1 (0.9)	0	-	-	-	-
Blood urea abnormal	n (%)	1 (0.9)	0	-	-	-	-
Blood uric acid increased	n (%)	1 (0.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Eosinophil count increased	n (%)	1 (0.9)	0	-	-	-	-
Platelet count decreased	n (%)	1 (0.9)	0	-	-	-	-
Red blood cell count decreased	n (%)	1 (0.9)	0	-	-	-	-

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Investigations							
Red blood cells urine positive	n (%)	1 (0.9)	0	-	-	-	-
White blood cells urine positive	n (%)	1 (0.9)	0	-	-	-	-
Injury, poisoning and procedural complications	n (%)	9 (8.2)	11 (10.1)	1.2596 (0.5001, 3.1726)	1.2334 (0.5324, 2.8576)	0.0191 (-0.0572, 0.0954) 0.6245	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications							
Fall	n (%)	4 (3.6)	3 (2.8)	-	-	-	-
				-	-	-	-
Procedural pain	n (%)	2 (1.8)	1 (0.9)	-	-	-	-
				-	-	-	-
Head injury	n (%)	0	2 (1.8)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications							
Rib fracture	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
				-	-	-	-
Contusion	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Face injury	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Injury, poisoning and procedural complications							
	Facial bones fracture	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Skin abrasion	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Skin laceration	n (%)	0	1 (0.9)	-	-	-
					-	-	-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications							
Tooth fracture	n (%)	0	1 (0.9)	-	-		-
				-	-		-
Hip fracture	n (%)	1 (0.9)	0	-	-		-
				-	-		-
Joint injury	n (%)	1 (0.9)	0	-	-		-
				-	-		-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications							
Traumatic haematoma	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Vascular disorders	n (%)	10 (9.1)	6 (5.5)	0.5825 (0.2041, 1.6627)	0.6055 (0.2280, 1.6083)	-0.0359 (-0.1046, 0.0328)	0.3090
Essential hypertension	n (%)	1 (0.9)	2 (1.8)	-	-	-	-
				-	-	-	-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Vascular disorders							
Hypotension	n (%)	2 (1.8)	1 (0.9)	-	-	-	-
				-	-	-	-
Syncope	n (%)	2 (1.8)	1 (0.9)	-	-	-	-
				-	-	-	-
Hypertension	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Vascular disorders							
Dizziness	n (%)	2 (1.8)	0	-	-	-	-
				-	-	-	-
Transient ischaemic attack	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Aortic arteriosclerosis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Vascular disorders							
Epistaxis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Pulmonary congestion	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Venous occlusion	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

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[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Metabolism and nutrition disorders	n (%)	8 (7.3)	6 (5.5)	0.7427 (0.2489, 2.2164)	0.7569 (0.2716, 2.1091)		-0.0177 (-0.0824, 0.0470) 0.5936
Hyperlipidaemia	n (%)	1 (0.9)	2 (1.8)	-	-		-
Vitamin D deficiency	n (%)	1 (0.9)	2 (1.8)	-	-		-

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Metabolism and nutrition disorders							
Dyslipidaemia	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Hyponatraemia	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Dehydration	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Metabolism and nutrition disorders							
Diabetes mellitus	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Glucose tolerance impaired	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Hyperkalaemia	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Metabolism and nutrition disorders							
Hypokalaemia	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Hypomagnesaemia	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Malnutrition	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders	n (%)	9 (8.2)	4 (3.7)	0.4275 (0.1276, 1.4323)	0.4485 (0.1424, 1.4131)		-0.0451 (-0.1073, 0.0171) 0.1586
Headache	n (%)	1 (0.9)	1 (0.9)	-	-		-
Dizziness	n (%)	0	1 (0.9)	-	-		-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Migraine	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Parkinson's disease	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Cerebral infarction	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Cerebral small vessel ischaemic disease	n (%)	1 (0.9)	0	-	-	-	-
Cerebrovascular accident	n (%)	1 (0.9)	0	-	-	-	-
Confusional state	n (%)	1 (0.9)	0	-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Dementia	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Embolic stroke	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Facial paralysis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Metabolic encephalopathy	n (%)	1 (0.9)	0	-	-	-	-
Sciatica	n (%)	1 (0.9)	0	-	-	-	-
Seizure	n (%)	1 (0.9)	0	-	-	-	-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Tremor	n (%)	1 (0.9)	0	-	-	-	-
Cardiac disorders	n (%)	4 (3.6)	8 (7.3)	2.0990 (0.6130, 7.1868)	2.0183 (0.6260, 6.5072)	0.0370 (-0.0231, 0.0972)	0.2297
Atrial fibrillation	n (%)	2 (1.8)	2 (1.8)	-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Cardiac disorders							
Cardiac failure congestive	n (%)	2 (1.8)	0	-	-	-	-
Pericardial effusion	n (%)	2 (1.8)	0	-	-	-	-
Acute myocardial infarction	n (%)	0	1 (0.9)	-	-	-	-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Cardiac disorders							
Aortic valve stenosis	n (%)	0	1 (0.9)	-	-	-	-
							-
Arrhythmia	n (%)	0	1 (0.9)	-	-	-	-
							-
Bradycardia	n (%)	0	1 (0.9)	-	-	-	-
							-

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MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Cardiac disorders							
Bundle branch block	n (%)	0	1 (0.9)	-	-	-	-
							-
Coronary artery disease	n (%)	0	1 (0.9)	-	-	-	-
							-
Myocardial infarction	n (%)	0	1 (0.9)	-	-	-	-
							-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Cardiac disorders							
Bundle branch block right	n (%)	1 (0.9)	0	-	-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	6 (5.5)	6 (5.5)	1.0097 (0.3153, 3.2336)	1.0092 (0.3359, 3.0322)	0.0005 (-0.0598, 0.0608)	0.9870
Squamous cell carcinoma of skin	n (%)	0	2 (1.8)	-	-	-	-

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Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acute leukaemia	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Basal cell carcinoma	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Keratoacanthoma	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-

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MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of the oral cavity	n (%)	0	1 (0.9)	-	-	-	-
Acrochordon	n (%)	1 (0.9)	0	-	-	-	-
Bladder cancer	n (%)	1 (0.9)	0	-	-	-	-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder cancer recurrent	n (%)	1 (0.9)	0	-	-	-	-
Bladder neoplasm	n (%)	1 (0.9)	0	-	-	-	-
Eye naevus	n (%)	1 (0.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Zero count correction was applied according to the method proposed by IQWiG.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Skin cancer	n (%)	1 (0.9)	0	-	-		-
				-	-		-
Squamous cell carcinoma of the tongue	n (%)	1 (0.9)	0	-	-		-
				-	-		-
Renal and urinary disorders	n (%)	6 (5.5)	5 (4.6)	0.8333 (0.2466, 2.8157)	0.8410 (0.2645, 2.6743)		-0.0087 (-0.0665, 0.0491) 0.7694

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders							
Haematuria	n (%)	3 (2.7)	1 (0.9)	-	-	-	-
				-	-	-	-
Cystitis	n (%)	0	2 (1.8)	-	-	-	-
				-	-	-	-
Dysuria	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Renal and urinary disorders							
Urinary tract infection	n (%)	0	1 (0.9)	-	-	-	-
							-
Acute kidney injury	n (%)	1 (0.9)	0	-	-	-	-
							-
Bladder diverticulum	n (%)	1 (0.9)	0	-	-	-	-
							-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders							
Haemorrhage urinary tract	n (%)	1 (0.9)	0	-	-	-	-
Nephrolithiasis	n (%)	1 (0.9)	0	-	-	-	-
Renal cyst	n (%)	1 (0.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Renal and urinary disorders							
Renal tubular necrosis		n (%)	1 (0.9)	0	-	-	-
					-	-	-
Urinary bladder haemorrhage		n (%)	1 (0.9)	0	-	-	-
					-	-	-
Urinary retention		n (%)	1 (0.9)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Musculoskeletal and connective tissue disorders	n (%)	3 (2.7)	5 (4.6)	-	-	-	-
Back pain	n (%)	1 (0.9)	2 (1.8)	-	-	-	-
Bursitis	n (%)	0	1 (0.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Ligament sprain		n (%)	0	1 (0.9)	-	-	-
					-	-	-
Plantar fasciitis		n (%)	0	1 (0.9)	-	-	-
					-	-	-
Hand fracture		n (%)	1 (0.9)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Joint swelling	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Pain in extremity	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Respiratory, thoracic and mediastinal disorders	n (%)	6 (5.5)	2 (1.8)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
Cough	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
Pleural effusion	n (%)	2 (1.8)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Epistaxis	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Respiratory failure	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Atelectasis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Hypoxia	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Nasal congestion	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Oropharyngeal pain	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pneumonia	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Pulmonary fibrosis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Pulmonary oedema	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Skin and subcutaneous tissue disorders	n (%)	2 (1.8)	4 (3.7)	-	-	-	-
Skin lesion	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
Ecchymosis	n (%)	0	1 (0.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Skin and subcutaneous tissue disorders	Eczema	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Tinea cruris	n (%)	0	1 (0.9)	-	-	-
Rash					-	-	-
		n (%)	1 (0.9)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
General disorders and administration site conditions	n (%)	4 (3.6)	2 (1.8)	-	-	-	-
Asthenia	n (%)	0	1 (0.9)	-	-	-	-
Death	n (%)	0	1 (0.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
General disorders and administration site conditions							
Cardiac death	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Gait inability	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Peripheral swelling	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
General disorders and administration site conditions							
Pyrexia	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Immune system disorders	n (%)	1 (0.9)	3 (2.8)	-	-	-	-
				-	-	-	-
Allergy to arthropod bite	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Zero count correction was applied according to the method proposed by IQWiG.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Immune system disorders							
Iodine allergy	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Seasonal allergy	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Allergic sinusitis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Blood and lymphatic system disorders	n (%)	2 (1.8)	2 (1.8)	-	-	-	-
Anaemia	n (%)	0	1 (0.9)	-	-	-	-
Microcytic anaemia	n (%)	0	1 (0.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Blood and lymphatic system disorders							
Blood loss anaemia		n (%)	1 (0.9)	0	-	-	-
					-	-	-
Lymphadenopathy		n (%)	1 (0.9)	0	-	-	-
					-	-	-
Psychiatric disorders		n (%)	1 (0.9)	2 (1.8)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Psychiatric disorders							
Anxiety	n (%)	0	2 (1.8)	-	-	-	-
				-	-	-	-
Stress	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Gastrointestinal disorders	n (%)	2 (1.8)	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Gastrointestinal disorders							
Small intestinal obstruction	n (%)	0	1 (0.9)	-	-		-
Gastrooesophageal reflux disease	n (%)	1 (0.9)	0	-	-		-
Melaena	n (%)	1 (0.9)	0	-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Gastrointestinal disorders							
Nausea	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Reproductive system and breast disorders	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
				-	-	-	-
Prostatomegaly	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Reproductive system and breast disorders							
Benign prostatic hyperplasia	n (%)	1 (0.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in
NORSE-2 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 TEAE	p-value [3]	0.8811
Eye disorders	p-value [3]	0.4267
Neovascular age-related macular degeneration	p-value [3]	0.4934
Visual acuity reduced	p-value [3]	0.0036
Conjunctival haemorrhage	p-value [3]	0.0591
Retinal haemorrhage	p-value [3]	0.1370
Infections and infestations	p-value [3]	0.4467
Urinary tract infection	p-value [3]	0.3956
Investigations	p-value [3]	0.5627
Injury, poisoning and procedural complications	p-value [3]	0.6401
Vascular disorders	p-value [3]	0.4517
Metabolism and nutrition disorders	p-value [3]	0.5824
Nervous system disorders	p-value [3]	0.2763

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Zero count correction was applied according to the method proposed by IQWiG.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

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Table Saf_88

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in
NORSE-2 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
Cardiac disorders	p-value [3]	0.1641
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	p-value [3]	>0.9999
Renal and urinary disorders	p-value [3]	0.7576

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_88

DATE: 16JUL2024 11:34

Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
At Least 1 Serious TEAE	n (%)	2 (40.0)	1 (25.0)	0.5000 (0.0279, 8.9517)	0.6250 (0.0839, 4.6570)		-0.1500 (-0.7537, 0.4537) 0.6547
Investigations	n (%)	0	1 (25.0)	-	-		-
Intraocular pressure increased	n (%)	0	1 (25.0)	-	-		-
Cardiac disorders	n (%)	1 (20.0)	0	-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_89

DATE: 16JUL2024 11:37

Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Cardiac disorders							
Cardiac arrest	n (%)	1 (20.0)	0	-	-	-	-
				-	-	-	-
Respiratory, thoracic and mediastinal disorders	n (%)	1 (20.0)	0	-	-	-	-
				-	-	-	-
Asthma	n (%)	1 (20.0)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_89

DATE: 16JUL2024 11:37

Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	
MedDRA Preferred Term	Statistic	Ranibizumab (Masked Data) (N=110)	(N=109)			p-value[2]	
At Least 1 Serious TEAE	n (%)	14 (12.7)	13 (11.9)	0.9286 (0.4147, 2.0794)	0.9371 (0.4621, 1.9002)	-0.0080 (-0.0951, 0.0791)	0.8573
Infections and infestations	n (%)	3 (2.7)	4 (3.7)	-	-	-	-
COVID-19	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
Clostridium difficile infection	n (%)	0	1 (0.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Infections and infestations							
Pneumonia	n (%)	0	1 (0.9)	-	-	-	-
Urinary tract infection	n (%)	0	1 (0.9)	-	-	-	-
COVID-19 pneumonia	n (%)	1 (0.9)	0	-	-	-	-
Pyelonephritis	n (%)	1 (0.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	(Masked Data)[1] (N=109)			
Cardiac disorders	n (%)	2 (1.8)	3 (2.8)	-	-	-
				-	-	-
Acute myocardial infarction	n (%)	0	1 (0.9)	-	-	-
				-	-	-
Aortic valve stenosis	n (%)	0	1 (0.9)	-	-	-
				-	-	-
Bundle branch block	n (%)	0	1 (0.9)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Cardiac disorders							
Myocardial infarction	n (%)	0	1 (0.9)	-	-	-	-
							-
							-
Bundle branch block right	n (%)	1 (0.9)	0	-	-	-	-
							-
Pericardial effusion	n (%)	1 (0.9)	0	-	-	-	-
							-
Nervous system disorders	n (%)	5 (4.5)	0	-	-	-	-
							-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_89

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Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Nervous system disorders							
Cerebral infarction	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Cerebrovascular accident	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Confusional state	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Embolic stroke	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_89

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Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders						
Seizure	n (%)	1 (0.9)	0	-	-	-
				-	-	-
Respiratory, thoracic and mediastinal disorders	n (%)	1 (0.9)	2 (1.8)	-	-	-
				-	-	-
Chronic obstructive pulmonary disease	n (%)	0	1 (0.9)	-	-	-
				-	-	-
Respiratory failure	n (%)	0	1 (0.9)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_89

DATE: 16JUL2024 11:37

Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pleural effusion	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	2 (1.8)	1 (0.9)	-	-	-	-
				-	-	-	-
Acute leukaemia	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Bladder neoplasm	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:37

Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of the tongue	n (%)	1 (0.9)	0	-	-	-	-
Vascular disorders	n (%)	2 (1.8)	1 (0.9)	-	-	-	-
Transient ischaemic attack	n (%)	0	1 (0.9)	-	-	-	-
Epistaxis	n (%)	1 (0.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_89

DATE: 16JUL2024 11:37

Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference
MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	(Masked Data)[1] (N=109)			95% CI p-value[2]
Vascular disorders						
Hypotension	n (%)	1 (0.9)	0	-	-	-
				-	-	-
General disorders and administration site conditions	n (%)	1 (0.9)	1 (0.9)	-	-	-
				-	-	-
Death	n (%)	0	1 (0.9)	-	-	-
				-	-	-
Cardiac death	n (%)	1 (0.9)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_89

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Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic	Ranibizumab (N=110)	(Masked Data)[1] (N=109)			
Injury, poisoning and procedural complications	n (%)	1 (0.9)	1 (0.9)	-	-	-
				-	-	-
Rib fracture	n (%)	0	1 (0.9)	-	-	-
				-	-	-
Hip fracture	n (%)	1 (0.9)	0	-	-	-
				-	-	-
Metabolism and nutrition disorders	n (%)	1 (0.9)	1 (0.9)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:37

Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Metabolism and nutrition disorders							
Hyponatraemia	n (%)	0	1 (0.9)	-	-		-
				-	-		-
Hypokalaemia	n (%)	1 (0.9)	0	-	-		-
				-	-		-
Renal and urinary disorders	n (%)	2 (1.8)	0	-	-		-
				-	-		-
Haemorrhage urinary tract	n (%)	1 (0.9)	0	-	-		-
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders							
Nephrolithiasis	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Musculoskeletal and connective tissue disorders	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Bursitis	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_89

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Table Saf_89

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 Serious TEAE	p-value [3]	>0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_89

DATE: 16JUL2024 11:37

Table Saf_90

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
At Least 1 Related TEAE	n (%)	0	2 (50.0)	11.0000 (0.3729, 324.5208)	6.0000 (0.3668, 98.1572)		0.4167 (-0.0742, 0.9076) 0.1407
Eye disorders	n (%)	0	1 (25.0)	4.7143 (0.1467, 151.4799)	3.6000 (0.1842, 70.3418)		0.2167 (-0.2419, 0.6752) 0.3764
Corneal abrasion	n (%)	0	1 (25.0)	-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Zero count correction was applied according to the method proposed by IQWiG.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_90

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic	Ranibizumab (N=5)	(Masked Data)[1] (N=4)			
Investigations	n (%)	0	1 (25.0)	-	-	-
				-	-	-
Intraocular pressure increased	n (%)	0	1 (25.0)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_90

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Statistic	ONS-5010 Ranibizumab (Masked Data)[1] (N=110) (N=109)		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
At Least 1 Related TEAE	n (%)	9 (8.2)	18 (16.5)	2.2198 (0.9499, 5.1874)	2.0183 (0.9486, 4.2944)	0.0833 (-0.0032, 0.1698) 0.0614	
Eye disorders	n (%)	6 (5.5)	17 (15.6)	3.2029 (1.2117, 8.4665)	2.8593 (1.1716, 6.9783)	0.1014 (0.0212, 0.1817) 0.0146	
Conjunctival haemorrhage	n (%)	2 (1.8)	9 (8.3)	4.8600 (1.0252, 23.0385)	4.5413 (1.0041, 20.5387)	0.0644 (0.0070, 0.1218) 0.0295	
Vitreous floaters	n (%)	0	3 (2.8)	- -	- -	- -	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_90

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Dry eye	n (%)	1 (0.9)	2 (1.8)	-	-	-	-
				-	-	-	-
Eye irritation	n (%)	0	2 (1.8)	-	-	-	-
				-	-	-	-
Vitreous haemorrhage	n (%)	0	2 (1.8)	-	-	-	-
				-	-	-	-
Corneal abrasion	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_90

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Punctate keratitis	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
				-	-	-	-
Iritis	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Photopsia	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Retinal pigment epithelial tear	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_90

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Conjunctival hyperaemia	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Dry age-related macular degeneration	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Eye pain	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

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Table Saf_90

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Subretinal fluid	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Investigations	n (%)	0	2 (1.8)	-	-	-	-
				-	-	-	-
Blood pressure increased	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_90

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications	n (%)	2 (1.8)	0	-	-	-	-
Procedural pain	n (%)	2 (1.8)	0	-	-	-	-
Cardiac disorders	n (%)	0	1 (0.9)	-	-	-	-
Acute myocardial infarction	n (%)	0	1 (0.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Zero count correction was applied according to the method proposed by IQWiG.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_90

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Immune system disorders	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Iodine allergy	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Nervous system disorders	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-
Cerebral infarction	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Zero count correction was applied according to the method proposed by IQWiG.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_90

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 Related TEAE	p-value [3]	0.1679
Eye disorders	p-value [3]	0.0362
Conjunctival haemorrhage	p-value [3]	0.0480

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Zero count correction was applied according to the method proposed by IQWiG.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_91

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes						
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious Related TEAE	n (%)	0	1 (25.0)	-	-	-
Investigations	n (%)	0	1 (25.0)	-	-	-
Intraocular pressure increased	n (%)	0	1 (25.0)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_91

DATE: 11JUL2024 5:06

Table Saf_91

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious Related TEAE	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
Cardiac disorders	n (%)	0	1 (0.9)	-	-	-	-
Acute myocardial infarction	n (%)	0	1 (0.9)	-	-	-	-
Nervous system disorders	n (%)	1 (0.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_91

DATE: 11JUL2024 5:06

Table Saf_91

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Nervous system disorders							
Cerebral infarction	n (%)	1 (0.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_91

DATE: 11JUL2024 5:06

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
At Least 1 TEAE		n (%)	4 (80.0)	3 (75.0)	0.7500 (0.0321, 17.5056)	0.9375 (0.4583, 1.9177)	-0.0500 (-0.6004, 0.5004) 0.8658	
Eye disorders	Grade 1	n (%)	4 (80.0)	2 (50.0)	0.2500 (0.0132, 4.7287)	0.6250 (0.2136, 1.8285)	-0.3000 (-0.9025, 0.3025) 0.3711	
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE	
	Grade 3	n (%)	0	0	-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
	Grade 5	n (%)	0	0	-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Corneal abrasion	Grade 1	n (%)	0	1 (25.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cystoid macular oedema	Grade 1	n (%)	0	1 (25.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Trichiasis	Grade 1	n (%)	0	1 (25.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal pigmentation	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Subretinal fluid	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Vision blurred	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations	Grade 1	n (%)	1 (20.0)	1 (25.0)	1.3333 (0.0571, 31.1210)	1.2500 (0.1089, 14.3432)	0.0500 (-0.5004, 0.6004) 0.8658
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Conjunctivitis	Grade 1	n (%)	0	1 (25.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Bronchitis	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	1 (25.0)	- -	- -	NE -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (25.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Cardiac disorders	Grade 1	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 2	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	1 (20.0)	0	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Cardiac arrest	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	1 (20.0)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Gastrointestinal disorders	Grade 1	n (%)	1 (20.0)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Nausea	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Nervous system disorders	Grade 1	n (%)	1 (20.0)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Nervous system disorders							
Headache	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Respiratory, thoracic and mediastinal disorders	Grade 1	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 2	n (%)	1 (20.0)	0	-	-	-	
					-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	0	0	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Asthma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Vascular disorders	Grade 1	n (%)	1 (20.0)	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Vascular disorders							
Hot flush	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No									
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]		
At Least 1 TEAE		n (%)	81 (73.6)	79 (72.5)	0.9428 (0.5189, 1.7130)	0.9843 (0.8380, 1.1561)	-0.0116 (-0.1291, 0.1059) 0.8470		
Eye disorders	Grade 1	n (%)	37 (33.6)	37 (33.9)	1.0139 (0.5791, 1.7750)	1.0092 (0.6965, 1.4622)	0.0031 (-0.1222, 0.1284) 0.9616		
	Grade 2	n (%)	18 (16.4)	10 (9.2)	0.5163 (0.2266, 1.1763)	0.5607 (0.2712, 1.1590)	-0.0719 (-0.1597, 0.0159) 0.1120		
	Grade 3	n (%)	1 (0.9)	1 (0.9)	-	-	-		
	Grade 4	n (%)	0	0	-	-	-		
	Grade 5	n (%)	0	0	-	-	-		

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No									
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]		
Eye disorders Neovascular age-related macular degeneration	Grade 1	n (%)	10 (9.1)	6 (5.5)	0.5825 (0.2041, 1.6627)	0.6055 (0.2280, 1.6083)	-0.0359 (-0.1046, 0.0328) 0.3090		
	Grade 2	n (%)	2 (1.8)	3 (2.8)	- -	- -	- -		
	Grade 3	n (%)	0	0	- -	- -	- -		
	Grade 4	n (%)	0	0	- -	- -	- -		
	Grade 5	n (%)	0	0	- -	- -	- -		

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No									
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]		
Eye disorders									
Visual acuity reduced	Grade 1	n (%)	9 (8.2)	2 (1.8)	0.2098 (0.0442, 0.9943)	0.2243 (0.0496, 1.0143)	-0.0635 (-0.1206, -0.0064) 0.0319		
	Grade 2	n (%)	8 (7.3)	1 (0.9)	- -	- -	- -		
	Grade 3	n (%)	0	0	- -	- -	- -		
	Grade 4	n (%)	0	0	- -	- -	- -		
	Grade 5	n (%)	0	0	- -	- -	- -		

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Eye disorders								
Conjunctival haemorrhage	Grade 1	n (%)	2 (1.8)	10 (9.2)	5.4545 (1.1665, 25.5064)	5.0459 (1.1316, 22.4989)	0.0736 (0.0139, 0.1332) 0.0170	
	Grade 2	n (%)	1 (0.9)	0	-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
	Grade 5	n (%)	0	0	-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal haemorrhage	Grade 1	n (%)	6 (5.5)	2 (1.8)	- -	- -	- -
	Grade 2	n (%)	2 (1.8)	1 (0.9)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Subretinal fluid	Grade 1	n (%)	1 (0.9)	2 (1.8)	-	-	-
					-	-	-
	Grade 2	n (%)	3 (2.7)	2 (1.8)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Dry eye	Grade 1	n (%)	4 (3.6)	3 (2.8)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous floaters	Grade 1	n (%)	1 (0.9)	5 (4.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Corneal abrasion	Grade 1	n (%)	0	3 (2.8)	- -	- -	- -
	Grade 2	n (%)	1 (0.9)	1 (0.9)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eye pain	Grade 1	n (%)	2 (1.8)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	2 (1.8)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Punctate keratitis	Grade 1	n (%)	2 (1.8)	2 (1.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous detachment	Grade 1	n (%)	2 (1.8)	3 (2.8)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Metamorphopsia	Grade 1	n (%)	4 (3.6)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cataract	Grade 1	n (%)	1 (0.9)	2 (1.8)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Dermatochalasis	Grade 1	n (%)	2 (1.8)	2 (1.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Subretinal fibrosis	Grade 1	n (%)	2 (1.8)	2 (1.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Posterior capsule opacification	Grade 1	n (%)	2 (1.8)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal oedema	Grade 1	n (%)	2 (1.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	2 (1.8)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cataract nuclear	Grade 1	n (%)	0	3 (2.8)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vision blurred	Grade 1	n (%)	1 (0.9)	2 (1.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous haemorrhage	Grade 1	n (%)	1 (0.9)	2 (1.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Hordeolum	Grade 1	n (%)	1 (0.9)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal degeneration	Grade 1	n (%)	2 (1.8)	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Dry age-related macular degeneration	Grade 1	n (%)	2 (1.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eye irritation	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Photopsia	Grade 1	n (%)	0	2 (1.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cataract	Grade 1	n (%)	1 (0.9)	1 (0.9)	-	-	-
cortical					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Macular scar	Grade 1	n (%)	1 (0.9)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal tear	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival hyperaemia	Grade 1	n (%)	2 (1.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Cystoid macular oedema	Grade 1	n (%)	2 (1.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Detachment of retinal pigment epithelium	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal vein occlusion	Grade 1	n (%)	2 (1.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Angle closure glaucoma	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Chorioretinopathy	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Choroidal neovascularisation	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctivitis allergic	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Dacryostenosis acquired	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eye swelling	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Iridocyclitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Iritis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Macular hole	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal pigment epithelial tear	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal pigmentation	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous opacities	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blepharitis	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blindness	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Entropion	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Exposure keratitis	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eyelid ptosis	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Foveal degeneration	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Macular fibrosis	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Macular oedema	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Macular pigmentation	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Meibomian gland dysfunction	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal detachment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Retinal drusen	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations	Grade 1	n (%)	7 (6.4)	7 (6.4)	1.0098 (0.3420, 2.9820)	1.0092 (0.3662, 2.7808)	0.0006 (-0.0642, 0.0654) 0.9859
	Grade 2	n (%)	4 (3.6)	6 (5.5)	1.5437 (0.4233, 5.6297)	1.5138 (0.4393, 5.2159)	0.0187 (-0.0366, 0.0740) 0.5088
	Grade 3	n (%)	2 (1.8)	3 (2.8)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	1 (0.9)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	4 (3.6)	3 (2.8)	- -	- -	- -
	Grade 2	n (%)	1 (0.9)	4 (3.7)	- -	- -	- -
	Grade 3	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19	Grade 1	n (%)	2 (1.8)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	2 (1.8)	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (0.9)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Sinusitis	Grade 1	n (%)	1 (0.9)	2 (1.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Bronchitis	Grade 1	n (%)	1 (0.9)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Acute sinusitis	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Clostridium difficile infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Fungal infection	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Influenza	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Upper respiratory tract infection	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Anogenital warts	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19 pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Cellulitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Herpes zoster	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Pyelonephritis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Sepsis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	Grade 1	n (%)	12 (10.9)	16 (14.7)	1.4050 (0.6310, 3.1283)	1.3456 (0.6682, 2.7097)	0.0377 (-0.0507, 0.1261) 0.4046
	Grade 2	n (%)	1 (0.9)	1 (0.9)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	1 (0.9)	6 (5.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure increased	Grade 1	n (%)	2 (1.8)	3 (2.8)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Urine analysis abnormal	Grade 1	n (%)	2 (1.8)	2 (1.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure diastolic decreased	Grade 1	n (%)	0	3 (2.8)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Bacterial test positive	Grade 1	n (%)	0	2 (1.8)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Haematocrit decreased	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Haemoglobin decreased	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Neutrophil count increased	Grade 1	n (%)	1 (0.9)	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cell count increased	Grade 1	n (%)	1 (0.9)	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood creatinine increased	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure diastolic increased	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood triglycerides increased	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Laboratory test abnormal	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Lymphocyte count decreased	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Monocyte count increased	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Protein urine present	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Urine leukocyte esterase positive	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Weight decreased	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Basophil count increased	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	1 (0.9)	0	-	-	-
creatinine							
abnormal	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea abnormal	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood uric acid increased	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Eosinophil count increased	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Platelet count decreased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cell count decreased	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cells urine positive	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	1 (0.9)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	5 (4.5)	6 (5.5)	1.2233 (0.3620, 4.1334)	1.2110 (0.3808, 3.8510)	0.0096 (-0.0483, 0.0675)	0.7458
	Grade 2	n (%)	3 (2.7)	4 (3.7)	-	-	-	-
	Grade 3	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Fall	Grade 1	n (%)	3 (2.7)	2 (1.8)	- -	- -	- -
	Grade 2	n (%)	1 (0.9)	1 (0.9)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Procedural pain	Grade 1	n (%)	1 (0.9)	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	1 (0.9)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Head injury	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	2 (1.8)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Rib fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Contusion	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Face injury	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Facial bones fracture	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Skin abrasion	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Skin laceration	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Tooth fracture	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Hip fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Joint injury	Grade 1	n (%)	1 (0.9)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Traumatic haematoma	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	1 (0.9)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders	Grade 1	n (%)	4 (3.6)	5 (4.6)	-	-	-
					-	-	-
	Grade 2	n (%)	4 (3.6)	0	-	-	-
					-	-	-
	Grade 3	n (%)	2 (1.8)	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Essential hypertension	Grade 1	n (%)	0	2 (1.8)	- -	- -	- -
	Grade 2	n (%)	1 (0.9)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypotension	Grade 1	n (%)	1 (0.9)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Syncope	Grade 1	n (%)	1 (0.9)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypertension	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Dizziness	Grade 1	n (%)	2 (1.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Transient ischaemic attack	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Aortic arteriosclerosis	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Epistaxis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Pulmonary congestion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Venous occlusion	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Metabolism and nutrition disorders	Grade 1	n (%)	6 (5.5)	4 (3.7)	0.6603 (0.1811, 2.4081)	0.6728 (0.1953, 2.3182)	-0.0178 (-0.0730, 0.0373)	0.5279
	Grade 2	n (%)	2 (1.8)	2 (1.8)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hyperlipidaemia	Grade 1	n (%)	1 (0.9)	2 (1.8)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Vitamin D deficiency	Grade 1	n (%)	1 (0.9)	2 (1.8)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Dyslipidaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hyponatraemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Dehydration	Grade 1	n (%)	1 (0.9)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition and disorders							
Diabetes mellitus	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Glucose tolerance impaired	Grade 1	n (%)	1 (0.9)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hyperkalaemia	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypokalaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypomagnesaemia	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Malnutrition	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders	Grade 1	n (%)	3 (2.7)	3 (2.8)	-	-	-
					-	-	-
	Grade 2	n (%)	4 (3.6)	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Headache	Grade 1	n (%)	1 (0.9)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Dizziness	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Migraine	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Parkinson's disease	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebral infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebral small vessel ischaemic disease	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebrovascular accident	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Confusional state	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Nervous system disorders							
Dementia	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Embololic stroke	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Facial paralysis	Grade 1	n (%)	1 (0.9)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Metabolic encephalopathy	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Sciatica	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Seizure	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Tremor	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders	Grade 1	n (%)	0	2 (1.8)	-	-	-
	Grade 2	n (%)	2 (1.8)	3 (2.8)	-	-	-
	Grade 3	n (%)	1 (0.9)	2 (1.8)	-	-	-
	Grade 4	n (%)	1 (0.9)	0	-	-	-
	Grade 5	n (%)	0	1 (0.9)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Atrial fibrillation	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	2 (1.8)	2 (1.8)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Cardiac failure congestive	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Pericardial effusion	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Acute myocardial infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Aortic valve stenosis	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Arrhythmia	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Bradycardia	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Bundle branch block	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Coronary artery disease	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Myocardial infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (0.9)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Bundle branch block right	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	3 (2.7)	2 (1.8)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	2 (1.8)	-	-	-
					-	-	-
	Grade 3	n (%)	2 (1.8)	2 (1.8)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of skin	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	2 (1.8)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acute leukaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Basal cell carcinoma	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Keratoacanthoma	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of the oral cavity	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acrochordon	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder cancer	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder cancer recurrent	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder neoplasm	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Eye naevus	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Skin cancer	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of the tongue	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders	Grade 1	n (%)	3 (2.7)	3 (2.8)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	2 (1.8)	-	-	-
					-	-	-
	Grade 3	n (%)	2 (1.8)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Haematuria	Grade 1	n (%)	2 (1.8)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Cystitis	Grade 1	n (%)	0	2 (1.8)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Dysuria	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Urinary tract infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Acute kidney injury	Grade 1	n (%)	1 (0.9)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Bladder diverticulum	Grade 1	n (%)	1 (0.9)	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Haemorrhage urinary tract	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Nephrolithiasis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Renal cyst	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Renal tubular necrosis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Urinary bladder haemorrhage	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Urinary retention	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	2 (1.8)	-	-	-	-
	Grade 2	n (%)	3 (2.7)	2 (1.8)	-	-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	2 (1.8)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Bursitis	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Ligament sprain	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Plantar fasciitis	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Hand fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Joint swelling	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Pain in extremity	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	3 (2.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	2 (1.8)	2 (1.8)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Cough	Grade 1	n (%)	1 (0.9)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pleural effusion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Epistaxis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Respiratory failure	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Atelectasis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Hypoxia	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Nasal congestion	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Oropharyngeal pain	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pulmonary fibrosis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pulmonary oedema	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	2 (1.8)	3 (2.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Skin lesion	Grade 1	n (%)	1 (0.9)	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Ecchymosis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders Eczema							
	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Tinea cruris	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Rash	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
General disorders and administration site conditions	Grade 1	n (%)	2 (1.8)	0	-	-	-	
					-	-	-	
	Grade 2	n (%)	1 (0.9)	1 (0.9)	-	-	-	
					-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	1 (0.9)	1 (0.9)	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Asthenia	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Death	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (0.9)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Cardiac death	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	1 (0.9)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Gait inability	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
Grade 4	n (%)	0	0		-	-	-
					-	-	-
Grade 5	n (%)	0	0		-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Peripheral swelling	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Pyrexia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders	Grade 1	n (%)	1 (0.9)	3 (2.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Allergy to arthropod bite	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Iodine allergy	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Seasonal allergy	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Allergic sinusitis	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders	Grade 1	n (%)	2 (1.8)	2 (1.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Anaemia	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Microcytic anaemia	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Blood loss anaemia	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Lymphadenopathy	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	1 (0.9)	-	-	-	-
	Grade 2	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Anxiety	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Stress	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders	Grade 1	n (%)	2 (1.8)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Small intestinal obstruction	Grade 1	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Gastroesophageal reflux disease	Grade 1	n (%)	1 (0.9)	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Melaena	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Nausea	Grade 1	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Reproductive system and breast disorders	Grade 1	n (%)	1 (0.9)	1 (0.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Reproductive system and breast disorders							
Prostatomegaly	Grade 1	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Reproductive system and breast disorders							
Benign prostatic hyperplasia	Grade 1	n (%)	1 (0.9)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group. NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Date of data extract: 26AUG2020

Table Saf_92

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic p-value [3]	Interaction
At Least 1 TEAE			0.8811
Eye disorders	Grade 1	p-value [3]	0.7814
	Grade 2	p-value [3]	0.1110
Neovascular age-related macular degeneration	Grade 1	p-value [3]	0.3046
Visual acuity reduced	Grade 1	p-value [3]	0.0480
Conjunctival haemorrhage	Grade 1	p-value [3]	0.0323
Infections and infestations	Grade 1	p-value [3]	>0.9999
	Grade 2	p-value [3]	0.5206
Investigations	Grade 1	p-value [3]	0.4210
Injury, poisoning and procedural complications	Grade 1	p-value [3]	0.7576
Metabolism and nutrition disorders	Grade 1	p-value [3]	0.5206

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.
[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_92

DATE: 16JUL2024 11:43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
At Least 1 Serious TEAE		n (%)	2 (40.0)	1 (25.0)	0.5000 (0.0279, 8.9517)	0.6250 (0.0839, 4.6570)	-0.1500 (-0.7537, 0.4537)	0.6547
Investigations	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	1 (25.0)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (25.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Cardiac disorders	Grade 1	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 2	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	1 (20.0)	0	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Cardiac arrest	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	1 (20.0)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	1 (20.0)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Asthma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
At Least 1 Serious TEAE		n (%)	14 (12.7)	13 (11.9)	0.9286 (0.4147, 2.0794)	0.9371 (0.4621, 1.9002)	-0.0080 (-0.0951, 0.0791) 0.8573	
Infections and infestations	Grade 1	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 2	n (%)	1 (0.9)	0	-	-	-	
					-	-	-	
	Grade 3	n (%)	2 (1.8)	3 (2.8)	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	0	1 (0.9)	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	1 (0.9)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Clostridium difficile infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Pneumonia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
COVID-19 pneumonia	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	1 (0.9)	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Pyelonephritis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

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Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Cardiac disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	1 (0.9)	2 (1.8)	-	-	-	-
	Grade 4	n (%)	1 (0.9)	0	-	-	-	-
	Grade 5	n (%)	0	1 (0.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Acute myocardial infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Aortic valve stenosis	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Bundle branch block	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Myocardial infarction	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	1 (0.9)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

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Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Bundle branch block right	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Cardiac disorders							
Pericardial effusion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Nervous system disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	3 (2.7)	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	1 (0.9)	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebral infarction	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Cerebrovascular accident	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Confusional state	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Embololic stroke	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Nervous system disorders							
Seizure	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	2 (1.8)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Respiratory failure	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Respiratory, thoracic and mediastinal disorders							
Pleural effusion	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	1 (0.9)	0	- -	- -	- -
	Grade 3	n (%)	1 (0.9)	1 (0.9)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acute leukaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Bladder neoplasm	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Squamous cell carcinoma of the tongue	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Vascular disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	2 (1.8)	1 (0.9)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Transient ischaemic attack	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Epistaxis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypotension	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Protocol ONS-5010-002

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
General disorders and administration site conditions	Grade 1	n (%)	0	0	-	-	-	
	Grade 2	n (%)	0	0	-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
	Grade 5	n (%)	1 (0.9)	1 (0.9)	-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Death	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	1 (0.9)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Cardiac death	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	1 (0.9)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	1 (0.9)	1 (0.9)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Rib fracture	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	1 (0.9)	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Hip fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

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Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Metabolism and nutrition disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (0.9)	1 (0.9)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

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Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hyponatraemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypokalaemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	2 (1.8)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Haemorrhage urinary tract	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Renal and urinary disorders							
Nephrolithiasis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (0.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Date of data extract: 26AUG2020

Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

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Table Saf_93

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Bursitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (0.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_93

DATE: 16JUL2024 11:46

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Interaction
MedDRA Preferred Term		p-value [3]	
At Least 1 Serious TEAE			>0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_94

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: Yes						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=5)	(Masked Data)[1] (N=4)			
At Least 1 TEAE Leading to Study Withdrawal	n (%)	1 (20.0)	0	-	-	-
				-	-	-
Cardiac disorders	n (%)	1 (20.0)	0	-	-	-
				-	-	-
Cardiac arrest	n (%)	1 (20.0)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_94

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Table Saf_94

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	4 (3.6)	2 (1.8)	-	-	-	-
				-	-	-	-
General disorders and administration site conditions	n (%)	0	2 (1.8)	-	-	-	-
Asthenia	n (%)	0	1 (0.9)	-	-	-	-
Death	n (%)	0	1 (0.9)	-	-	-	-
				-	-	-	-
Eye disorders	n (%)	2 (1.8)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_94

DATE: 11JUL2024 5:18

Table Saf_94

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Eye disorders							
Retinal oedema	n (%)	1 (0.9)	0	-	-		-
				-	-		-
Subretinal fluid	n (%)	1 (0.9)	0	-	-		-
				-	-		-
Visual acuity reduced	n (%)	1 (0.9)	0	-	-		-
				-	-		-
Nervous system disorders	n (%)	1 (0.9)	0	-	-		-
				-	-		-
Cerebral infarction	n (%)	1 (0.9)	0	-	-		-
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_94

DATE: 11JUL2024 5:18

Table Saf_94

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-2 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data)[1] (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Respiratory, thoracic and mediastinal disorders	n (%)	1 (0.9)	0	-	-	-	-
Pulmonary fibrosis	n (%)	1 (0.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_94

DATE: 11JUL2024 5:18

Table Saf_107

Severe AE (CTCAE Grade ≥ 3) by Age in NORSE-2 Study
(Safety Population)

< 80 years						
Parameter	Statistic	ONS-5010		Odds Ratio	Relative Risk	Absolute Risk
		Ranibizumab (N=54)	(Masked Data)[1] (N=62)			Difference
At Least 1 TEAE(CTCAE Grade ≥ 3)	n (%)	4 (7.4)	7 (11.3)	1.5909 (0.4393, 5.7609)	1.5242 (0.4716, 4.9259)	0.0388 (-0.0665, 0.1441) 0.4784

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_107

Severe AE (CTCAE Grade ≥ 3) by Age in NORSE-2 Study
(Safety Population)

≥ 80 years						
Parameter	Statistic	Ranibizumab (N=61)	ONS-5010 (Masked Data) (N=51)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE(CTCAE Grade ≥ 3)	n (%)	9 (14.8)	7 (13.7)	0.9192 (0.3165, 2.6696)	0.9303 (0.3726, 2.3228)	-0.0103 (-0.1401, 0.1195) 0.8774

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_107

Severe AE (CTCAE Grade ≥ 3) by Age in NORSE-2 Study
(Safety Population)

Parameter	Statistic	Interaction
At Least 1 TEAE(CTCAE Grade ≥ 3)	p-value [3]	0.5560

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_107

DATE: 16SEP2024 12:21

Table Saf_108

Severe AE (CTCAE Grade ≥ 3) by Gender in NORSE-2 Study
(Safety Population)

Male						
Parameter	Statistic	Ranibizumab (N=46)	ONS-5010 (Masked Data)[1] (N=46)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE(CTCAE Grade ≥ 3)	n (%)	5 (10.9)	8 (17.4)	1.7263 (0.5193, 5.7394)	1.6000 (0.5656, 4.5264)	0.0652 (-0.0765, 0.2070) 0.3719

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_108

Severe AE (CTCAE Grade ≥ 3) by Gender in NORSE-2 Study
 (Safety Population)

Female						
Parameter	Statistic	Ranibizumab (N=69)	ONS-5010 (Masked Data)[1] (N=67)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE(CTCAE Grade ≥ 3)	n (%)	8 (11.6)	6 (9.0)	0.7500 (0.2456, 2.2904)	0.7724 (0.2831, 2.1074)	-0.0264 (-0.1283, 0.0755) 0.6139

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_108

Severe AE (CTCAE Grade ≥ 3) by Gender in NORSE-2 Study
(Safety Population)

Parameter	Statistic	Interaction
At Least 1 TEAE(CTCAE Grade ≥ 3)	p-value [3]	0.3312

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_108

DATE: 16SEP2024 12:29

Table Saf_109

Severe AE (CTCAE Grade ≥ 3) by Previous Anti-VEGF in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes						
Parameter	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) [1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value [2]
At Least 1 TEAE (CTCAE Grade ≥ 3)	n (%)	1 (20.0)	0	0.3333 (0.0105, 10.5744)	0.4000 (0.0205, 7.8158)	-0.1500 (-0.5850, 0.2850) 0.5403

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Zero count correction was applied according to the method proposed by IQWiG.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_109

Severe AE (CTCAE Grade ≥ 3) by Previous Anti-VEGF in NORSE-2 Study
 (Safety Population)

Previous Anti VEGF Therapy: No						
Parameter	Statistic	ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference
		Ranibizumab (N=110)	(Masked Data)[1] (N=109)			95% CI p-value[2]
At Least 1 TEAE(CTCAE Grade ≥ 3)	n (%)	12 (10.9)	14 (12.8)	1.2035 (0.5295, 2.7355)	1.1774 (0.5707, 2.4288)	0.0193 (-0.0663, 0.1050) 0.6588

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_109

Severe AE (CTCAE Grade ≥ 3) by Previous Anti-VEGF in NORSE-2 Study
(Safety Population)

Parameter	Statistic	Interaction
At Least 1 TEAE(CTCAE Grade ≥ 3)	p-value [3]	0.5394

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Zero count correction was applied according to the method proposed by IQWiG.

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_109

DATE: 16SEP2024 12:35

Table Saf_110

Non-Severe AE (CTCAE Grade <3) by Age in NORSE-2 Study
(Safety Population)

< 80 years						
Parameter	Statistic	Ranibizumab (N=54)	ONS-5010 (Masked Data) (N=62)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE(CTCAE Grade <3)	n (%)	39 (72.2)	38 (61.3)	0.6090 (0.2778,1.3347)	0.8486 (0.6557,1.0983)	-0.1093 (-0.2795,0.0609) 0.2158

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_110

Non-Severe AE (CTCAE Grade <3) by Age in NORSE-2 Study
(Safety Population)

>= 80 years						
Parameter	Statistic	ONS-5010		Odds Ratio	Relative Risk	Absolute Risk
		Ranibizumab (N=61)	(Masked Data)[1] (N=51)			Difference
At Least 1 TEAE(CTCAE Grade <3)	n (%)	44 (72.1)	38 (74.5)	1.1294 (0.4863, 2.6227)	1.0330 (0.8258, 1.2921)	0.0238 (-0.1404, 0.1880) 0.7781

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_110

Non-Severe AE (CTCAE Grade <3) by Age in NORSE-2 Study
(Safety Population)

Parameter	Statistic	Interaction
At Least 1 TEAE(CTCAE Grade <3)	p-value [3]	0.2755

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_110

DATE: 16SEP2024 12:40

Table Saf_111

Non-Severe AE (CTCAE Grade <3) by Gender in NORSE-2 Study
 (Safety Population)

Male						
Parameter	Statistic	ONS-5010		Odds Ratio	Relative Risk	Absolute Risk Difference
		Ranibizumab (N=46)	(Masked Data)[1] (N=46)			
At Least 1 TEAE(CTCAE Grade <3)	n (%)	35 (76.1)	31 (67.4)	0.6495 (0.2599, 1.6233)	0.8857 (0.6842, 1.1466)	-0.0870 (-0.2701, 0.0962) 0.3570

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_111

Non-Severe AE (CTCAE Grade <3) by Gender in NORSE-2 Study
(Safety Population)

Female						
Parameter	Statistic	ONS-5010		Odds Ratio	Relative Risk	Absolute Risk Difference
		Ranibizumab (N=69)	(Masked Data) (N=67)			
At Least 1 TEAE(CTCAE Grade <3)	n (%)	48 (69.6)	45 (67.2)	0.8949 (0.4342,1.8443)	0.9655 (0.7680,1.2138)	-0.0240 (-0.1803,0.1323) 0.7642

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_111

Non-Severe AE (CTCAE Grade <3) by Gender in NORSE-2 Study
(Safety Population)

Parameter	Statistic	Interaction
At Least 1 TEAE(CTCAE Grade <3)	p-value [3]	0.7300

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_111

DATE: 16SEP2024 12:45

Table Saf_112

Non-Severe AE (CTCAE Grade <3) by Previous Anti-VEGF in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes						
Parameter	Statistic	ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
		Ranibizumab (N=5)	(Masked Data)[1] (N=4)			
At Least 1 TEAE(CTCAE Grade <3)	n (%)	4 (80.0)	3 (75.0)	0.7500 (0.0321,17.5056)	0.9375 (0.4583,1.9177)	-0.0500 (-0.6004,0.5004) 0.8658

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_112

Non-Severe AE (CTCAE Grade <3) by Previous Anti-VEGF in NORSE-2 Study
(Safety Population)

Previous Anti VEGF Therapy: No						
Parameter	Statistic	Ranibizumab (N=110)	ONS-5010 (Masked Data) (N=109)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE(CTCAE Grade <3)	n (%)	79 (71.8)	73 (67.0)	0.7957 (0.4473, 1.4156)	0.9325 (0.7818, 1.1123)	-0.0485 (-0.1704, 0.0735) 0.4376

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_112

Non-Severe AE (CTCAE Grade <3) by Previous Anti-VEGF in NORSE-2 Study
(Safety Population)

Parameter	Statistic	Interaction
At Least 1 TEAE(CTCAE Grade <3)	p-value [3]	0.4713

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_112

DATE: 16SEP2024 12:50

Table Morb_1

Subjects Gaining >=15 Letters from Baseline to 11 Months in NORSE-1 Study
(ITT Population)

Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Number of Subjects, n/N1 (%) [1]	5/ 24 (20.8)	2/ 26 (7.7)
Odds Ratio [2] 95% CI	0.3167 (0.0279, 2.2505)	
Relative Risk [2] 95% CI	0.3692 (0.0501, 1.7689)	
Absolute Risk Reduction [2] 95% CI	-0.1314 (-0.3550, 0.0765)	
p-value [3]	0.2387	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_1

DATE: 11JUN2024 11:17

Table Morb_1

Subjects Gaining >=15 Letters from Baseline to 11 Months in NORSE-1 Study
 (ITT Population)

Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Number of Subjects, n/N (%) [1]	5/ 30 (16.7)	2/ 31 (6.5)
Odds Ratio [2] 95% CI	0.3448 (0.0308, 2.3739)	
Relative Risk [2] 95% CI	0.3871 (0.0501, 1.8874)	
Absolute Risk Reduction [2] 95% CI	-0.1022 (-0.2885, 0.0721)	
p-value [3]	0.2554	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_1

DATE: 11JUN2024 11:17

Table Morb_2

Subjects Gaining >=10 Letters from Baseline to 11 Months in NORSE-1 Study
 (ITT Population)

Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Number of Subjects, n/N1 (%) [1]	9/ 24 (37.5)	3/ 26 (11.5)
Odds Ratio [2] 95% CI	0.2174 (0.0336, 1.0895)	
Relative Risk [2] 95% CI	0.3077 (0.0626, 0.9528)	
Absolute Risk Reduction [2] 95% CI	-0.2596 (-0.4953, -0.0171)	
p-value [3]	0.0475	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_2

DATE: 11JUN2024 11:19

Table Morb_2

Subjects Gaining >=10 Letters from Baseline to 11 Months in NORSE-1 Study
 (ITT Population)

Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Number of Subjects, n/N (%) [1]	9/ 30 (30.0)	3/ 31 (9.7)
Odds Ratio [2] 95% CI	0.2500 (0.0397, 1.1893)	
Relative Risk [2] 95% CI	0.3226 (0.0653, 1.0151)	
Absolute Risk Reduction [2] 95% CI	-0.2032 (-0.4110, 0.0025)	
p-value [3]	0.0586	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_2

DATE: 11JUN2024 11:19

Table Morb_3

Subjects Gaining >=5 Letters from Baseline to 11 Months in NORSE-1 Study
 (ITT Population)

Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Number of Subjects, n/N1 (%) [1]	11/ 24 (45.8)	11/ 26 (42.3)
Odds Ratio [2] 95% CI	0.8667 (0.2457, 3.0560)	
Relative Risk [2] 95% CI	0.9231 (0.4762, 1.7872)	
Absolute Risk Reduction [2] 95% CI	-0.0353 (-0.3101, 0.2544)	
p-value [3]	>0.9999	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_3

DATE: 11JUN2024 11:20

Table Morb_3

Subjects Gaining >=5 Letters from Baseline to 11 Months in NORSE-1 Study
 (ITT Population)

Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Number of Subjects, n/N (%) [1]	11/ 30 (36.7)	11/ 31 (35.5)
Odds Ratio [2] 95% CI	0.9500 (0.2940, 3.0712)	
Relative Risk [2] 95% CI	0.9677 (0.4776, 1.9761)	
Absolute Risk Reduction [2] 95% CI	-0.0118 (-0.2545, 0.2326)	
p-value [3]	>0.9999	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_3

DATE: 11JUN2024 11:20

Table Morb_4

Subjects Loosing < 15 Letters from Baseline to 11 Months in NORSE-1 Study
 (ITT Population)

Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Number of Subjects, n/N1 (%) [1]	20/ 24 (83.3)	23/ 26 (88.5)
Odds Ratio [2] 95% CI	1.5333 (0.2269, 11.6540)	
Relative Risk [2] 95% CI	1.0615 (0.8123, 1.4222)	
Absolute Risk Reduction [2] 95% CI	0.0513 (-0.1616, 0.2702)	
p-value [3]	0.6971	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_4

DATE: 11JUN2024 11:36

Table Morb_4

Subjects Loosing < 15 Letters from Baseline to 11 Months in NORSE-1 Study
 (ITT Population)

Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Number of Subjects, n/N (%) [1]	20/ 30 (66.7)	23/ 31 (74.2)
Odds Ratio [2] 95% CI	1.4375 (0.4145, 5.0732)	
Relative Risk [2] 95% CI	1.1129 (0.7858, 1.6278)	
Absolute Risk Reduction [2] 95% CI	0.0753 (-0.1593, 0.3086)	
p-value [3]	0.5824	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_4

DATE: 11JUN2024 11:36

Table Morb_5

BCVA Change from Baseline - Trimmed Means Fixed Approach in NORSE-1 Study
 (ITT Population)

Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
BCVA Score Change from Baseline to 11 Months [1]	n	20	23
	Mean (SD)	8.0 (9.30)	3.2 (8.33)
	Median	8.0	4.0
	Min, Max	-5, 27	-14, 20
LS Means (Q1, Q3) [2]		9.441 (8.417, 10.530)	9.187 (8.215, 10.265)
(95% CI)		(6.104, 12.296)	(5.950, 11.934)
LS Means Difference			-0.254
(95% CI)			(-6.230, 5.764)
p-value			0.7411
Corrected Hedges' G (95% CI)			-3.4861 (-4.4466, -2.5256)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means fixed approach compares the 50% best (> median) observations in each treatment arm. Those observations with missing data at 11 months had values worse than the median imputed to calculate the adjusted median in which the best 50% were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by taking the 2.5 and 97.5 percentiles from the same permutation distribution. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 2250.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] Q1 = 25th percentile, Q3 = 75th percentile.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_5

DATE: 14MAY2024 12:36

Table Morb_6

BCVA Change from Baseline - Trimmed Means Adaptive Approach in NORSE-1 Study
(ITT Population)

Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
BCVA Score Change from Baseline to 11 Months [1]	n	20	23
	Mean (SD)	8.0 (9.30)	3.2 (8.33)
	Median	8.0	4.0
	Min, Max	-5, 27	-14, 20
LS Means (Q1, Q3) [2]		5.417 (4.445, 6.382)	6.272 (4.963, 7.522)
(95% CI)		(2.644, 8.235)	(2.814, 10.093)
LS Means Difference			0.856
(95% CI)			(-5.150, 6.999)
p-value			0.8318
Corrected Hedges' G (95% CI)			10.6502 (8.2801, 13.0204)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means adaptive approach assigns a percentile floor in the treatment arm based on the greatest proportion of dropouts observed between the two arms. Those observations with missing data at 11 months had values worse than the percentile floor imputed to calculate the adjusted floor in which the best observations were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by taking the 2.5 and 97.5 percentiles from the same permutation distribution. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 2830.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] Q1 = 25th percentile, Q3 = 75th percentile.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_6

DATE: 14MAY2024 12:39

Table Morb_7

BCVA Change from Baseline - Analysis of Covariance in NORSE-1 Study
(ITT Population)

Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
BCVA Score Change from Baseline to 11 Months [1]	n	20	23
	Mean (SD)	8.0 (9.30)	3.2 (8.33)
	Median	8.0	4.0
	Min, Max	-5, 27	-14, 20
LS Means (SE)		7.820 (1.9884)	3.331 (1.8531)
(95% CI)		(3.801, 11.838)	(-0.415, 7.076)
LS Means Difference (SE)			-4.489 (2.7292)
(95% CI)			(-10.005, 1.027)
p-value [2]			0.1078
Corrected Hedges' G (95% CI)			-0.4957 (-1.1044, 0.1130)

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_7

DATE: 27MAY2024 4:27

Table Morb_8

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation in NORSE-1 Study
(ITT Population)

Parameter [1]	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
BCVA Score Change from Baseline to 11 Months [2]	n	20	23
	Mean (SD)	8.0 (9.30)	3.2 (8.33)
	Median	8.0	4.0
	Min, Max	-5, 27	-14, 20
LS Means (SE)		7.294 (2.6419)	2.963 (2.4456)
(95% CI)		(2.106, 12.482)	(-1.836, 7.762)
LS Means Difference (SE)			-4.331 (3.5844)
(95% CI)			(-11.367, 2.705)
p-value [3]			0.2273
Corrected Hedges' G (95% CI)			-0.3612 (-0.9655, 0.2430)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_8

DATE: 27MAY2024 4:31

Table Morb_9

BCVA Change from Baseline over Time - Repeated Measures
(ITT Population)

Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Day 30	BCVA Score Change from Baseline	n	29	28
		Mean (SD)	5.3 (7.32)	2.5 (6.60)
		Median	5.0	2.0
		Min, Max	-9, 24	-11, 22
		LS Means (SE) [1] (95% CI)	5.276 (1.5365) (2.212, 8.340)	2.464 (1.5637) (-0.654, 5.583)
		LS Means Difference (SE) (95% CI)		-2.812 (2.1923) (-7.183, 1.560)
		p-value		0.2039
		Corrected Hedges' G (95% CI)		-0.3351 (-0.8582, 0.1879)
Day 60	BCVA Score Change from Baseline	n	28	27
		Mean (SD)	5.5 (7.71)	2.5 (6.05)
		Median	7.0	1.0
		Min, Max	-10, 20	-10, 14
		LS Means (SE) [1] (95% CI)	5.548 (1.4426) (2.665, 8.431)	2.642 (1.4684) (-0.292, 5.577)
		LS Means Difference (SE) (95% CI)		-2.906 (2.0584) (-7.020, 1.208)
		p-value		0.1629
		Corrected Hedges' G (95% CI)		-0.3754 (-0.9088, 0.1580)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_9

BCVA Change from Baseline over Time - Repeated Measures
(ITT Population)

Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Day 90	BCVA Score Change from Baseline	n	28	27
		Mean (SD)	6.6 (7.97)	3.9 (7.16)
		Median	8.0	5.0
		Min, Max	-14, 20	-24, 14
	LS Means (SE) [1]		6.616 (1.5026)	4.073 (1.5296)
	(95% CI)		(3.624, 9.608)	(1.027, 7.119)
	LS Means Difference (SE)			-2.543 (2.1442)
	(95% CI)			(-6.812, 1.727)
Day 120	BCVA Score Change from Baseline	n	27	26
		Mean (SD)	6.8 (9.85)	2.2 (6.75)
		Median	8.0	2.5
		Min, Max	-13, 29	-11, 14
	LS Means (SE) [1]		6.161 (1.6594)	1.408 (1.6898)
	(95% CI)		(2.865, 9.458)	(-1.949, 4.765)
	LS Means Difference (SE)			-4.754 (2.3683)
	(95% CI)			(-9.458, -0.049)
	p-value			0.2393
	Corrected Hedges' G (95% CI)			-0.3153 (-0.8473, 0.2167)
	BCVA Score Change from Baseline	n	27	26
		Mean (SD)	6.8 (9.85)	2.2 (6.75)
		Median	8.0	2.5
		Min, Max	-13, 29	-11, 14
	LS Means (SE) [1]		6.161 (1.6594)	1.408 (1.6898)
	(95% CI)		(2.865, 9.458)	(-1.949, 4.765)
	LS Means Difference (SE)			-4.754 (2.3683)
	(95% CI)			(-9.458, -0.049)
	p-value			0.0477
	Corrected Hedges' G (95% CI)			-0.5434 (-1.0920, 0.0053)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_9

BCVA Change from Baseline over Time - Repeated Measures
(ITT Population)

Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Day 150	BCVA Score Change from Baseline	n	26	24
		Mean (SD)	5.6 (7.26)	2.1 (7.77)
		Median	4.0	2.0
		Min, Max	-5, 24	-12, 14
	LS Means (SE) [1]		5.132 (1.5573)	2.019 (1.5939)
	(95% CI)		(2.031, 8.233)	(-1.154, 5.193)
	LS Means Difference (SE)			-3.113 (2.2284)
	(95% CI)			(-7.550, 1.325)
Day 180	BCVA Score Change from Baseline	n	26	25
		Mean (SD)	7.3 (8.58)	2.6 (7.88)
		Median	6.5	3.0
		Min, Max	-8, 27	-10, 18
	LS Means (SE) [1]		6.821 (1.5126)	2.134 (1.5409)
	(95% CI)		(3.811, 9.832)	(-0.933, 5.201)
	LS Means Difference (SE)			-4.687 (2.1593)
	(95% CI)			(-8.985, -0.389)
	p-value			0.1665
	Corrected Hedges' G (95% CI)			-0.3889 (-0.9491, 0.1713)
	BCVA Score Change from Baseline	n	26	25
		Mean (SD)	7.3 (8.58)	2.6 (7.88)
		Median	6.5	3.0
		Min, Max	-8, 27	-10, 18
	LS Means (SE) [1]		6.821 (1.5126)	2.134 (1.5409)
	(95% CI)		(3.811, 9.832)	(-0.933, 5.201)
	LS Means Difference (SE)			-4.687 (2.1593)
	(95% CI)			(-8.985, -0.389)
	p-value			0.0330
	Corrected Hedges' G (95% CI)			-0.5986 (-1.1602, -0.0371)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_9

BCVA Change from Baseline over Time - Repeated Measures
(ITT Population)

Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Day 210	BCVA Score Change from Baseline	n	24	24
		Mean (SD)	6.2 (10.59)	2.9 (7.45)
		Median	6.0	4.5
		Min, Max	-22, 33	-11, 14
	LS Means (SE) [1] (95% CI)		5.860 (1.6695) (2.542, 9.177)	2.525 (1.6894) (-0.832, 5.883)
	LS Means Difference (SE) (95% CI)			-3.334 (2.3751) (-8.054, 1.386)
	p-value			0.1639
	Corrected Hedges' G (95% CI)			-0.3986 (-0.9702, 0.1730)
Day 240	BCVA Score Change from Baseline	n	21	23
		Mean (SD)	8.1 (9.62)	2.3 (6.71)
		Median	9.0	3.0
		Min, Max	-5, 38	-10, 12
	LS Means (SE) [1] (95% CI)		6.723 (1.5080) (3.721, 9.725)	2.118 (1.5015) (-0.873, 5.109)
	LS Means Difference (SE) (95% CI)			-4.605 (2.1281) (-8.843, -0.367)
	p-value			0.0336
	Corrected Hedges' G (95% CI)			-0.6402 (-1.2472, -0.0331)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_9

BCVA Change from Baseline over Time - Repeated Measures
(ITT Population)

Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Day 270	BCVA Score Change from Baseline	n	20	23
		Mean (SD)	6.7 (12.29)	2.4 (7.85)
		Median	7.5	2.0
		Min, Max	-16, 38	-13, 14
	LS Means (SE) [1] (95% CI)		5.532 (1.8546) (1.849, 9.215)	1.914 (1.7988) (-1.659, 5.487)
	LS Means Difference (SE) (95% CI)			-3.618 (2.5837) (-8.749, 1.513)
	p-value			0.1647
	Corrected Hedges' G (95% CI)			-0.4191 (-1.0251, 0.1869)
Day 300	BCVA Score Change from Baseline	n	20	22
		Mean (SD)	7.3 (10.13)	2.7 (7.01)
		Median	10.0	3.0
		Min, Max	-12, 25	-12, 17
	LS Means (SE) [1] (95% CI)		5.536 (1.7852) (1.985, 9.087)	2.732 (1.7402) (-0.730, 6.195)
	LS Means Difference (SE) (95% CI)			-2.804 (2.4930) (-7.763, 2.156)
	p-value			0.2641
	Corrected Hedges' G (95% CI)			-0.3405 (-0.9506, 0.2696)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_9

BCVA Change from Baseline over Time - Repeated Measures
(ITT Population)

Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Day 330	BCVA Score Change from Baseline	n	20	23
		Mean (SD)	8.0 (9.30)	3.2 (8.33)
		Median	8.0	4.0
		Min, Max	-5, 27	-14, 20
	LS Means (SE) [1]		6.507 (1.7317)	2.964 (1.6782)
	(95% CI)		(3.063, 9.952)	(-0.375, 6.304)
	LS Means Difference (SE)			-3.543 (2.4115)
	(95% CI)			(-8.340, 1.254)
Day 365	BCVA Score Change from Baseline	p-value		0.1456
		Corrected Hedges' G (95% CI)		-0.4397 (-1.0464, 0.1670)
		n		23
		Mean (SD)		1.9 (8.59)
		Median		2.0
		Min, Max		-12, 20

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_9

DATE: 14MAY2024 13:41

Table Morb_10

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months in NORSE-1 Study (ITT Population)

Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Number of Subjects, n/N1 (%) [1]	5/ 24 (20.8)	4/ 26 (15.4)
Odds Ratio [2] 95% CI	0.6909 (0.1197, 3.7611)	
Relative Risk [2] 95% CI	0.7385 (0.1933, 2.8876)	
Absolute Risk Reduction [2] 95% CI	-0.0545 (-0.2922, 0.1777)	
p-value [3]	0.7210	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing. 20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_10

DATE: 11JUN2024 11:39

Table Morb_10

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months in NORSE-1 Study (ITT Population)

Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Number of Subjects, n/N (%) [1]	5/ 30 (16.7)	4/ 31 (12.9)
Odds Ratio [2] 95% CI	0.7407 (0.1319, 3.8982)	
Relative Risk [2] 95% CI	0.7742 (0.1943, 3.0594)	
Absolute Risk Reduction [2] 95% CI	-0.0376 (-0.2386, 0.1547)	
p-value [3]	0.7315	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing. 20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_10

DATE: 11JUN2024 11:39

Table Morb_101

Summary of Subgroup Interaction tests (p-values) for All Morbidity Endpoints in NORSE-1 Study (ITT Population)

Population	End point	Subgroups				
		Age	Gender	Prior Anti-VEGF Therapy	Baseline BCVA Score	Prior Anti-VEGF Therapy and Baseline BCVA Score
N1	Subjects Gaining ≥ 15 Letters from Baseline to 11 Months	NE	NE	NE	NE	NE
	Subjects Gaining ≥ 10 Letters from Baseline to 11 Months	NE	NE	NE	NE	NE
	Subjects Gaining ≥ 5 Letters from Baseline to 11 Months	0.1476	0.4861	0.5263	0.6421	NE
	Subjects Loosing < 15 Letters from Baseline to 11 Months	0.7694	0.1653	0.3000	0.5099	0.4077
	Subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months	NE	NE	NE	NE	NE
	Subjects Loosing ≤ 10 Letters from Baseline to 11 Months	0.5194	0.1149	0.2238	0.8749	0.3414

N1 = number of subjects with Month 11 assessment. N = number of subjects in ITT population.

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing. 20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_101

DATE: 19JUN2024 13:34

Table Morb_101

Summary of Subgroup Interaction tests (p-values) for All Morbidity Endpoints in NORSE-1 Study (ITT Population)

Population	End point	Subgroups				
		Age	Gender	Prior Anti-VEGF Therapy	Baseline BCVA Score	Prior Anti-VEGF Therapy and Baseline BCVA Score
N	Subjects Gaining ≥ 15 Letters from Baseline to 11 Months	NE	NE	NE	NE	NE
	Subjects Gaining ≥ 10 Letters from Baseline to 11 Months	NE	NE	NE	NE	NE
	Subjects Gaining ≥ 5 Letters from Baseline to 11 Months	0.0934	0.4641	0.3793	0.7206	NE
	Subjects Loosing < 15 Letters from Baseline to 11 Months	0.6326	0.2361	0.9075	0.5351	0.9328
	Subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months	NE	NE	NE	NE	NE
	Subjects Loosing ≤ 10 Letters from Baseline to 11 Months	0.8490	0.1666	0.7531	0.7880	0.9592

N1 = number of subjects with Month 11 assessment. N = number of subjects in ITT population.

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing. 20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_101

DATE: 19JUN2024 13:34

Table Morb_103

Subjects Loosing <=10 Letters from Baseline to 11 Months in NORSE-1 Study
 (ITT Population)

Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Number of Subjects, n/N1 (%) [1]	20/ 24 (83.3)	22/ 26 (84.6)
Odds Ratio [2] 95% CI	1.1000 (0.1788, 6.7459)	
Relative Risk [2] 95% CI	1.0154 (0.7641, 1.3827)	
Absolute Risk Reduction [2] 95% CI	0.0128 (-0.2163, 0.2449)	
p-value [3]	>0.9999	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_103

DATE: 11JUN2024 12:19

Table Morb_103

Subjects Loosing <=10 Letters from Baseline to 11 Months in NORSE-1 Study
 (ITT Population)

Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Number of Subjects, n/N (%) [1]	20/ 30 (66.7)	22/ 31 (71.0)
Odds Ratio [2] 95% CI	1.2222 (0.3603, 4.1747)	
Relative Risk [2] 95% CI	1.0645 (0.7338, 1.5526)	
Absolute Risk Reduction [2] 95% CI	0.0430 (-0.1938, 0.2777)	
p-value [3]	0.7863	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.6.1

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class		ONS-5010				Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data) (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
At Least 1 TEAE	n (%)	20 (66.7)	25 (80.6)	2.0833 (0.5624, 8.1739)	1.2097 (0.8849, 1.7614)	0.1398 (-0.0884, 0.3696) 0.2546
Eye disorders	n (%)	12 (40.0)	16 (51.6)	1.6000 (0.5171, 4.9878)	1.2903 (0.7281, 2.5479)	0.1161 (-0.1407, 0.3696) 0.4443
Conjunctival haemorrhage	n (%)	2 (6.7)	5 (16.1)	2.6923 (0.3916, 30.1331)	2.4194 (0.4964, 18.7705)	0.0946 (-0.0870, 0.2777) 0.4248
Visual acuity reduced	n (%)	4 (13.3)	1 (3.2)	0.2167 (0.0043, 2.4253)	0.2419 (0.0095, 1.6903)	-0.1011 (-0.2777, 0.0543) 0.1953
Eye pain	n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	0.0620 (-, -)* NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
Eye disorders						
Posterior capsule opacification	n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	0.0620 (-, -)* NE
Blepharitis	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
Lacrimation increased	n (%)	2 (6.7)	0	0.1810 (-, -)*	NE (NE, NE)	-0.0650 (-, -)* NE
Neovascular age-related macular degeneration	n (%)	2 (6.7)	0	0.1810 (-, -)*	NE (NE, NE)	-0.0650 (-, -)* NE
Blindness transient	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
Eye disorders						
Choroidal neovascularisation	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Conjunctivitis allergic	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Corneal scar	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Dry eye	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Keratopathy	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
Eye disorders						
Lenticular opacities	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Punctate keratitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Seasonal allergy	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Subretinal fluid	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Visual impairment	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
Eye disorders						
Vitreous detachment	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Abnormal sensation in eye	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Cataract	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Diabetic retinal oedema	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Scleromalacia	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	ONS-5010 Ranibizumab (Masked Data)[1]		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI
		(N=30)	(N=31)			pvalue
Investigations	n (%)	8 (26.7)	9 (29.0)	1.1250 (0.3171, 4.0374)	1.0887 (0.4671, 2.8510)	0.0237 (-0.2152,0.2522) >0.9999
White blood cells urine positive	n (%)	4 (13.3)	4 (12.9)	0.9630 (0.1612, 5.7572)	0.9677 (0.2314, 4.0496)	-0.0043 (-0.1948,0.1836) >0.9999
Blood urea increased	n (%)	3 (10.0)	1 (3.2)	0.3000 (0.0055, 4.0675)	0.3226 (0.0126, 3.0533)	-0.0677 (-0.2387,0.0870) 0.3540
Blood creatinine increased	n (%)	1 (3.3)	2 (6.5)	2.0000 (0.0979,121.9959)	1.9355 (0.1795,52.4812)	0.0312 (-0.1194,0.1836) >0.9999
Blood triglycerides increased	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293,32.1244)	-0.0011 (-0.1516,0.1395) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
Investigations						
Eosinophil count increased	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
Intraocular pressure increased	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
Protein urine present	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
Blood albumin increased	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Blood pressure systolic increased	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations						
Platelet morphology abnormal	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Red blood cell rouleaux formation present	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Red blood cells urine positive	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Urinary casts	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Aspartate aminotransferase increased	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
Investigations						
Blood glucose increased	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Blood lactate dehydrogenase increased	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Blood sodium increased	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Platelet count decreased	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Infections and infestations	n (%)	3 (10.0)	6 (19.4)	2.1600 (0.4031, 14.5994)	1.9355 (0.5307, 14.2625)	0.0935 (-0.0982, 0.2878) 0.4729

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
Infections and infestations						
Urinary tract infection	n (%)	0	3 (9.7)	7.4912 (-, -)*	NE (NE, NE)	0.0932 (-, -)* NE
Influenza	n (%)	2 (6.7)	1 (3.2)	0.4667 (0.0077, 9.5433)	0.4839 (0.0179, 5.2203)	-0.0344 (-0.1920, 0.1124) 0.6124
Lower respiratory tract infection	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
Candida infection	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Endophthalmitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
Infections and infestations						
Kidney infection	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Tooth infection	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Conjunctivitis	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Musculoskeletal and connective tissue disorders	n (%)	4 (13.3)	2 (6.5)	0.4483 (0.0381, 3.4716)	0.4839 (0.0653, 2.6086)	-0.0688 (-0.2492, 0.1005) 0.4248
Back pain	n (%)	2 (6.7)	1 (3.2)	0.4667 (0.0077, 9.5433)	0.4839 (0.0179, 5.2203)	-0.0344 (-0.1920, 0.1124) 0.6124

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
Musculoskeletal and connective tissue disorders						
Rheumatoid arthritis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Ankle fracture	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Wrist fracture	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Gastrointestinal disorders	n (%)	2 (6.7)	2 (6.5)	0.9655 (0.0658, 14.1812)	0.9677 (0.0661, 14.2626)	-0.0022 (-0.1635, 0.1549) >0.9999
Diarrhoea	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
Gastrointestinal disorders						
Pancreatitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Tooth abscess	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Vomiting	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Blood and lymphatic system disorders	n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	0.0620 (-, -)* NE
Lymphadenopathy	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Blood and lymphatic system disorders						
Macrocytosis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Renal and urinary disorders	n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	0.0620 (-, -)* NE
Glycosuria	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Renal tubular acidosis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Injury, poisoning and procedural complications	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Injury, poisoning and procedural complications						
Macular scar	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Contusion	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
Basal cell carcinoma	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
Psychiatric disorders	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
Psychiatric disorders						
Confusional state	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Insomnia	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Vascular disorders	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
Dizziness	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Hypertension	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

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* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1]	Odds Ratio	Relative Risk	Difference
				95% CI	95% CI	95% CI
General disorders and administration site conditions	n (%)	2 (6.7)	0	0.1810 (-, -)*	NE (NE, NE)	-0.0650 (-, -)* NE
Injection site pain	n (%)	2 (6.7)	0	0.1810 (-, -)*	NE (NE, NE)	-0.0650 (-, -)* NE
Skin and subcutaneous tissue disorders	n (%)	2 (6.7)	0	0.1810 (-, -)*	NE (NE, NE)	-0.0650 (-, -)* NE
Brow ptosis	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Skin laceration	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI pvalue
Endocrine disorders	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Hyperthyroidism	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Immune system disorders	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Seasonal allergy	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Metabolism and nutrition disorders	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_1

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1]	Odds Ratio	Relative Risk	Difference
			(N=31)	95% CI	95% CI	95% CI
						pvalue
Metabolism and nutrition disorders						
Hypercholesterolaemia	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Type 2 diabetes mellitus	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_1

DATE: 25JUL2024 10:34

Table Saf_2

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)			pvalue
At Least 1 Serious TEAE	n (%)	2 (6.7)	4 (12.9)	2.0741 (0.2682, 24.4258)	1.9355 (0.3592, 14.3815)	0.0624 (-0.1129, 0.2466) 0.6713
Eye disorders	n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	0.0620 (-, -)* NE
Blindness transient	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Visual impairment	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Infections and infestations	n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	0.0620 (-, -)* NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_2

DATE: 26JUL2024 6:00

Table Saf_2

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1]	Odds Ratio	Relative Risk	Difference
			(N=31)	95% CI	95% CI	95% CI
						pvalue
Infections and						
infestations						
Endophthalmitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Lower respiratory tract	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
infection						
Musculoskeletal and	n (%)	2 (6.7)	0	0.1810 (-, -)*	NE (NE, NE)	-0.0650 (-, -)*
connective tissue						
disorders						
Ankle fracture	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Back pain	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_2

DATE: 26JUL2024 6:00

Table Saf_2

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class		ONS-5010 Ranibizumab (Masked Data)[1]				Absolute Risk Difference
MedDRA Preferred Term	Statistic	(N=30)	(N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI pvalue
Investigations	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Intraocular pressure increased	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_2

DATE: 26JUL2024 6:00

Table Saf_3

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
At Least 1 TEAE Related to Study Medication Administration Procedure		n (%)	6 (20.0)	9 (29.0)	1.6364 (0.4325, 6.5232)	1.4516 (0.5868, 4.0515)	0.0903 (-0.1346, 0.3086) 0.5541
Eye disorders		n (%)	4 (13.3)	8 (25.8)	2.2609 (0.5144, 11.5064)	1.9355 (0.6305, 10.7532)	0.1247 (-0.0870, 0.3392) 0.3354
Conjunctival haemorrhage		n (%)	2 (6.7)	4 (12.9)	2.0741 (0.2682, 24.4258)	1.9355 (0.3592, 14.3815)	0.0624 (-0.1129, 0.2466) 0.6713
Eye pain		n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	0.0620 (-, -)* NE
Blindness transient		n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_3

DATE: 20JUN2024 12:07

Table Saf_3

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders						
Corneal scar	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Keratopathy	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Punctate keratitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Abnormal sensation in eye	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
Lacrimation increased	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_3

DATE: 20JUN2024 12:07

Table Saf_3

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
Intraocular pressure increased	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
General disorders and administration site conditions	n (%)	2 (6.7)	0	0.1810 (-, -)*	NE (NE, NE)	-0.0650 (-, -)* NE
Injection site pain	n (%)	2 (6.7)	0	0.1810 (-, -)*	NE (NE, NE)	-0.0650 (-, -)* NE
Infections and infestations	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_3

DATE: 20JUN2024 12:07

Table Saf_3

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
MedDRA Preferred Term						
Infections and infestations						
Endophthalmitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_3

DATE: 20JUN2024 12:07

Table Saf_4

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class		ONS-5010				Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	(Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI
At Least 1 TEAE Related to Study Drug	n (%)	4 (13.3)	3 (9.7)	0.6964 (0.0936, 4.5767)	0.7258 (0.1084, 3.1858)	-0.0366 (-0.2208,0.1516) 0.7072
Eye disorders	n (%)	3 (10.0)	2 (6.5)	0.6207 (0.0487, 5.9035)	0.6452 (0.0655, 3.8133)	-0.0355 (-0.2152,0.1274) 0.6713
Blindness transient	n (%)	0	1 (3.2)	NE (NE,NE)	NE (NE,NE)	0.0323 (-0.0884,0.1670) >0.9999
Eye pain	n (%)	0	1 (3.2)	NE (NE,NE)	NE (NE,NE)	0.0323 (-0.0884,0.1670) >0.9999
Abnormal sensation in eye	n (%)	1 (3.3)	0	NE (NE,NE)	NE (NE,NE)	-0.0333 (-0.1744,0.0870) 0.4918

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_4

DATE: 26JUL2024 7:03

Table Saf_4

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders						
Cataract	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Lacrimation increased	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Investigations	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
Intraocular pressure increased	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
Infections and infestations	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_4

DATE: 26JUL2024 7:03

Table Saf_4

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations						
Endophthalmitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
General disorders and administration site conditions	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
Injection site pain	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_4

DATE: 26JUL2024 7:03

Table Saf_5

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	ONS-5010 Ranibizumab (Masked Data)[1]		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI
		(N=30)	(N=31)			pvalue
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	7 (23.3)	9 (29.0)	1.3442 (0.3685, 5.0404)	1.2442 (0.4963, 3.1859)	0.0570 (-0.1747, 0.2804) 0.7723
Eye disorders	n (%)	5 (16.7)	8 (25.8)	1.7391 (0.4241, 7.7272)	1.5484 (0.5563, 5.2203)	0.0914 (-0.1237, 0.3086) 0.5339
Conjunctival haemorrhage	n (%)	2 (6.7)	4 (12.9)	2.0741 (0.2682, 24.4258)	1.9355 (0.3592, 14.3815)	0.0624 (-0.1129, 0.2466) 0.6713
Eye pain	n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	0.0620 (-, -)* NE
Blindness transient	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_5

DATE: 20JUN2024 14:52

Table Saf_5

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
	Corneal scar	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Keratopathy	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Punctate keratitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Abnormal sensation in eye	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Cataract	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_5

DATE: 20JUN2024 14:52

Table Saf_5

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders						
Lacrimation increased	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
Investigations	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
Intraocular pressure increased	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
General disorders and administration site conditions	n (%)	2 (6.7)	0	0.1810 (-, -)*	NE (NE, NE)	-0.0650 (-, -)* NE
Injection site pain	n (%)	2 (6.7)	0	0.1810 (-, -)*	NE (NE, NE)	-0.0650 (-, -)* NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_5

DATE: 20JUN2024 14:52

Table Saf_5

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study
 (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	ONS-5010 Ranibizumab (Masked Data)[1]		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI
		(N=30)	(N=31)			pvalue
Infections and infestations	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Endophthalmitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_5

DATE: 20JUN2024 14:52

Table Saf_6

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
At Least 1 Serious TEAE Related to Study Drug	n (%)	0	2 (6.5)	NE (NE, NE)	NE (NE, NE)	0.0620 (-, -)* NE
Eye disorders	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Blindness transient	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Infections and infestations	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Endophthalmitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_6

DATE: 21JUN2024 5:35

Table Saf_6

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Intraocular pressure increased	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_6

DATE: 21JUN2024 5:35

Table Saf_7

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
At Least 1 Serious TEAE Related to Study Medication Administration Procedure	n (%)	0	2 (6.5)	NE (NE, NE)	NE (NE, NE)	0.0620 (-, -)* NE
Eye disorders	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Blindness transient	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Infections and infestations	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Endophthalmitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_7

DATE: 21JUN2024 8:35

Table Saf_7

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Intraocular pressure increased	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_7

DATE: 21JUN2024 8:35

Table Saf_8

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
At Least 1 Serious TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	0	2 (6.5)	NE (NE, NE)	NE (NE, NE)	0.0620 (-, -)* NE
Eye disorders	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Blindness transient	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Infections and infestations	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Endophthalmitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_8

DATE: 21JUN2024 8:55

Table Saf_8

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Intraocular pressure increased	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ. p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_8

DATE: 21JUN2024 8:55

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
At Least 1 TEAE		n (%)	20 (66.7)	25 (80.6)	2.0833 (0.5624, 8.1739)	1.2097 (0.8849, 1.7614)	0.1398 (-0.0884, 0.3696) 0.2546
Eye disorders	Grade 1	n (%)	7 (23.3)	10 (32.3)	1.5646 (0.4393, 5.7715)	1.3825 (0.6031, 3.3864)	0.0892 (-0.1516, 0.3144) 0.5700
	Grade 2	n (%)	4 (13.3)	4 (12.9)	0.9630 (0.1612, 5.7572)	0.9677 (0.2314, 4.0496)	-0.0043 (-0.1948, 0.1836) >0.9999
	Grade 3	n (%)	1 (3.3)	2 (6.5)	2.0000 (0.0979, 121.9959)	1.9355 (0.1795, 52.4812)	0.0312 (-0.1194, 0.1836) >0.9999
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	2 (6.7)	5 (16.1)	2.6923 (0.3916, 30.1331)	2.4194 (0.4964,18.7705)	0.0946 (-0.0870,0.2777) 0.4248
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	3 (10.0)	0	0.1247 (-, -)*	NE (NE, NE)	-0.0973 (-, -)* NE
	Grade 3	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Eye pain	Grade 1	n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	0.0620 (-, -)*
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Posterior capsule opacification	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	NE 0.0620 (-, -)*
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Blepharitis	Grade 1	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Lacrimation increased	Grade 1	n (%)	2 (6.7)	0	0.1810 (-, -)*	NE (NE, NE)	-0.0650 (-, -)* NE
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Neovascular age-related macular degeneration	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Blindness transient	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Choroidal neovascularisation	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Conjunctivitis allergic	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Corneal scar	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670) >0.9999
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Dry eye	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Keratopathy	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Lenticular opacities	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

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MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Punctate keratitis	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Seasonal allergy	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670) >0.9999
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Subretinal fluid	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670) >0.9999
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Visual impairment	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Vitreous detachment	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Abnormal sensation in eye	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Cataract	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Diabetic retinal oedema	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Scleromalacia	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations	Grade 1	n (%)	7 (23.3)	8 (25.8)	1.1429 (0.3035, 4.3767)	1.1060 (0.4307, 3.0595)	0.0247 (-0.2014, 0.2466) >0.9999
	Grade 2	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
White blood cells urine positive	Grade 1	n (%)	4 (13.3)	4 (12.9)	0.9630 (0.1612, 5.7572)	0.9677 (0.2314, 4.0496)	-0.0043 (-0.1948, 0.1836) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Blood urea increased	Grade 1	n (%)	3 (10.0)	1 (3.2)	0.3000 (0.0055, 4.0675)	0.3226 (0.0126, 3.0533)	-0.0677 (-0.2387, 0.0870) 0.3540
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Blood creatinine increased	Grade 1	n (%)	1 (3.3)	2 (6.5)	2.0000 (0.0979, 121.9959)	1.9355 (0.1795, 52.4812)	0.0312 (-0.1194, 0.1836) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Blood triglycerides increased	Grade 1	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Eosinophil count increased	Grade 1	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Intraocular pressure increased	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670) >0.9999
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Protein urine present	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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p-value was calculated using PROC FREQ by Fisher's exact test method.

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NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Blood albumin increased	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Blood pressure systolic increased	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

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NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Platelet morphology abnormal	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Red blood cell rouleaux formation present	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Red blood cells urine positive	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Urinary casts	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Aspartate aminotransferase increased	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Blood glucose increased	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in
NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Blood lactate dehydrogenase increased	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Blood sodium increased	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Platelet count decreased	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations	Grade 1	n (%)	3 (10.0)	4 (12.9)	1.3333 (0.2031, 9.9346)	1.2903 (0.2941, 8.6780)	0.0290 (-0.1528, 0.2152) >0.9999
	Grade 2	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	3 (9.7)	7.4912 (-, -)*	NE (NE, NE)	0.0932 (-, -)*
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations							
Influenza	Grade 1	n (%)	2 (6.7)	1 (3.2)	0.4667 (0.0077, 9.5433)	0.4839 (0.0179, 5.2203)	-0.0344 (-0.1920, 0.1124) 0.6124
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

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NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations							
Candida infection	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations							
Endophthalmitis	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

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NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations							
Kidney infection	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations							
Tooth infection	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations							
Conjunctivitis	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
	Grade 2	n (%)	2 (6.7)	1 (3.2)	0.4667 (0.0077, 9.5433)	0.4839 (0.0179, 5.2203)	-0.0344 (-0.1920, 0.1124) 0.6124
	Grade 3	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 3	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Musculoskeletal and connective tissue disorders							
Rheumatoid arthritis	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Musculoskeletal and connective tissue disorders							
Ankle fracture	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	NE 0.0333 (-0.0870, 0.1744) 0.4918
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Musculoskeletal and connective tissue disorders							
Wrist fracture	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	NE 0.0333 (-0.0870, 0.1744) 0.4918
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Gastrointestinal disorders	Grade 1	n (%)	2 (6.7)	2 (6.5)	0.9655 (0.0658, 14.1812)	0.9677 (0.0661,14.2626)	-0.0022 (-0.1635,0.1549) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Gastrointestinal disorders							
Diarrhoea	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Gastrointestinal disorders							
Pancreatitis	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Gastrointestinal disorders							
Tooth abscess	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Gastrointestinal disorders							
Vomiting	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Blood and lymphatic system disorders	Grade 1	n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	0.0620 (-, -)*
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Blood and lymphatic system disorders							
Lymphadenopathy	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

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NE = Not estimable

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Blood and lymphatic system disorders							
Macrocytosis	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Renal and urinary disorders	Grade 1	n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	0.0620 (-, -)*
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Renal and urinary disorders							
Glycosuria	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Renal and urinary disorders							
Renal tubular acidosis	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Injury, poisoning and procedural complications	Grade 1	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Injury, poisoning and procedural complications							
Macular scar	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Injury, poisoning and procedural complications							
Contusion	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 2	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Basal cell carcinoma	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	NE -0.0011 (-0.1516, 0.1395) >0.9999
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Psychiatric disorders	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	NE -0.0011 (-0.1516, 0.1395) >0.9999
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Psychiatric disorders							
Confusional state	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670) >0.9999
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Psychiatric disorders							
Insomnia	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	NE 0.0333 (-0.0870, 0.1744) 0.4918
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

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NE = Not estimable

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Vascular disorders	Grade 1	n (%)	1 (3.3)	1 (3.2)	0.9667 (0.0119, 78.4650)	0.9677 (0.0293, 32.1244)	-0.0011 (-0.1516, 0.1395) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Vascular disorders							
Dizziness	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

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NE = Not estimable

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Vascular disorders							
Hypertension	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
General disorders and administration site conditions	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
General disorders and administration site conditions							
Injection site pain	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Skin and subcutaneous tissue disorders	Grade 1	n (%)	2 (6.7)	0	0.1810 (-, -)*	NE (NE, NE)	-0.0650 (-, -)*
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Skin and subcutaneous tissue disorders							
Brow ptosis	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Skin and subcutaneous tissue disorders							
Skin laceration	Grade 1	n (%)	1 (3.3)	0	NE (NE, NE)	1.0345 (0.9127, 1.2095)	0.0333 (-0.0870, 0.1744) 0.4918
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Endocrine disorders	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Endocrine disorders							
Hyperthyroidism	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Immune system disorders	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Immune system disorders							
Seasonal allergy	Grade 1	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Metabolism and nutrition disorders	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Metabolism and nutrition disorders							
Hypercholesterolemia	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670) >0.9999
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_9

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Metabolism and nutrition disorders							
Type 2 diabetes mellitus	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670) >0.9999
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_9

DATE: 21JUN2024 14:15

Table Saf_10

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
At Least 1 Serious TEAE		n (%)	2 (6.7)	4 (12.9)	2.0741 (0.2682, 24.4258)	1.9355 (0.3592, 14.3815)	0.0624 (-0.1129, 0.2466) 0.6713
Eye disorders	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	2 (6.5)	5.1695 (-, -)*	NE (NE, NE)	0.0620 (-, -)*
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_10

DATE: 26JUL2024 9:26

Table Saf_10
Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Blindness transient	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_10

DATE: 26JUL2024 9:26

Table Saf_10
Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Eye disorders							
Visual impairment	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_10

DATE: 26JUL2024 9:26

Table Saf_10
Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670) >0.9999
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670) >0.9999
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_10

DATE: 26JUL2024 9:26

Table Saf_10

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations							
Endophthalmitis	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_10

DATE: 26JUL2024 9:26

Table Saf_10

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670) >0.9999
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_10

DATE: 26JUL2024 9:26

Table Saf_10

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 2	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
	Grade 3	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	-0.0333 (-0.1744, 0.0870) 0.4918
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_10

DATE: 26JUL2024 9:26

Table Saf_10

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Musculoskeletal and connective tissue disorders							
Ankle fracture	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	NE -0.0333 (-0.1744, 0.0870) 0.4918
	Grade 3	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_10

DATE: 26JUL2024 9:26

Table Saf_10

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	1 (3.3)	0	NE (NE, NE)	NE (NE, NE)	NE -0.0333 (-0.1744, 0.0870) 0.4918
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_10

DATE: 26JUL2024 9:26

Table Saf_10

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670) >0.9999
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_10

DATE: 26JUL2024 9:26

Table Saf_10
Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Investigations							
Intraocular pressure increased	Grade 1	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 2	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 3	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	NE 0.0323 (-0.0884, 0.1670)
	Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
	Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

* There is not enough data to perform Chi-Square Test

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_10

DATE: 26JUL2024 9:26

Table Saf_11

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	ONS-5010 Ranibizumab (Masked Data)[1]		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI
		(N=30)	(N=31)			pvalue
At Least 1 TEAE Leading to Study Withdrawal	n (%)	3 (10.0)	3 (9.7)	0.9643 (0.1186, 7.8507)	0.9677 (0.1676, 5.5910)	-0.0032 (-0.1835, 0.1730) >0.9999
Eye disorders	n (%)	3 (10.0)	2 (6.5)	0.6207 (0.0487, 5.9035)	0.6452 (0.0655, 3.8133)	-0.0355 (-0.2152, 0.1274) 0.6713
Visual acuity reduced	n (%)	3 (10.0)	1 (3.2)	0.3000 (0.0055, 4.0675)	0.3226 (0.0126, 3.0533)	-0.0677 (-0.2387, 0.0870) 0.3540
Subretinal fluid	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999
Infections and infestations	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_11

DATE: 21JUN2024 9:54

Table Saf_11

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=30)	ONS-5010 (Masked Data)[1] (N=31)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
Infections and infestations	Endophthalmitis	n (%)	0	1 (3.2)	NE (NE, NE)	NE (NE, NE)	0.0323 (-0.0884, 0.1670) >0.9999

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_11

DATE: 21JUN2024 9:54

Table Saf_95

Summary of all Safety subgroups related analyses (p-values) in NORSE-1 Study
(Safety Population)

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term					
MedDRA System Organ Class MedDRA Preferred Term	Subgroups				
	Age	Gender	Prior Anti-VEGF Therapy	Baseline BCVA Score	Prior Anti-VEGF Therapy and Baseline BCVA Score
At Least 1 TEAE	0.5113	0.4425	0.0373	0.6748	0.0932
Eye disorders	0.2536	0.2908	0.3769	0.1160	0.0648
Investigations	0.8368	0.8555	-	0.4448	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
Zero count correction was applied according to the method proposed by IQWiG.
p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_95

DATE: 16JUL2024 10:25

Table Saf_95

Summary of all Safety subgroups related analyses (p-values) in NORSE-1 Study
 (Safety Population)

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term					
Subgroups					
MedDRA System Organ Class MedDRA Preferred Term	Age	Gender	Prior Anti-VEGF Therapy	Baseline BCVA Score	Prior Anti-VEGF Therapy and Baseline BCVA Score
At Least 1 TEAE Related to Study Medication Administration Procedure	-	-	0.4688	-	-
Eye disorders	-	-	0.9292	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.
 For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
 p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
 Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_95

DATE: 16JUL2024 10:25

Table Saf_95

Summary of all Safety subgroups related analyses (p-values) in NORSE-1 Study
 (Safety Population)

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term					
Subgroups					
MedDRA System Organ Class MedDRA Preferred Term	Age	Gender	Prior Anti-VEGF Therapy	Baseline BCVA Score	Prior Anti-VEGF Therapy and Baseline BCVA Score
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	0.5113	-	0.7557	0.4425	-
Eye disorders	-	-	0.7302	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
 p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
 Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_95

DATE: 16JUL2024 10:25

Table Saf_95

Summary of all Safety subgroups related analyses (p-values) in NORSE-1 Study
(Safety Population)

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade Subgroups						
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Age	Gender	Prior Anti-VEGF Therapy	Baseline BCVA Score	Prior Anti-VEGF Therapy and Baseline BCVA Score
At Least 1 TEAE		0.5113	0.4425	0.0373	0.6748	0.0932
Eye disorders	Grade 1	0.1368	0.8555	0.6091	0.8555	-
Investigations	Grade 1	-	0.9522	-	0.5051	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_95

DATE: 16JUL2024 10:25

Table Saf_100
Treatment-Emergent Adverse Events by Maximum CTCAE Severity Grade in NORSE-1 Study (Safety Population)

Characteristic	Statistic	ONS-5010 Ranibizumab (Masked Data)[1]		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI pvalue
		(N=30)	(N=31)			
At Least 1 TEAE	n (%)	20 (66.7)	25 (80.6)	2.0833 (0.6463, 6.7160)	1.2097 (0.8906, 1.6431)	0.1398 (-0.0788, 0.3584) 0.2185
Maximum Severity						
CTCAE Grade 1	n (%)	9 (30.0)	15 (48.4)	2.1875 (0.7642, 6.2614)	1.6129 (0.8366, 3.1097)	0.1839 (-0.0566, 0.4244) 0.1450
CTCAE Grade 2	n (%)	9 (30.0)	6 (19.4)	0.5600 (0.1713, 1.8311)	0.6452 (0.2616, 1.5913)	-0.1065 (-0.3215, 0.1086) 0.3384
CTCAE Grade 3	n (%)	2 (6.7)	4 (12.9)	2.0741 (0.3505, 12.2719)	1.9355 (0.3825, 9.7944)	0.0624 (-0.0856, 0.2103) 0.4174
CTCAE Grade 4	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
CTCAE Grade 5	n (%)	0	0	NE (NE, NE)	NE (NE, NE)	NE (NE, NE) NE

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events. For maximum severity, subject incidence rates are reported; therefore a subject contributes only once to each summary for their highest severity.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ.

p-value was calculated using PROC FREQ by Fisher's exact test method.

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_101

Treatment-Emergent Adverse Events by severe (CTCAE Severity Grade ≥ 3) / non-severe (CTCAE Severity Grade < 3) in
NORSE-1 Study
(Safety Population)

Characteristic	Statistic	ONS-5010 Ranibizumab (Masked Data)[1]		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference
		(N=30)	(N=31)			95% CI
At Least 1 TEAE	n (%)	20 (66.7)	25 (80.6)	2.0833 (0.6463, 6.7160)	1.2097 (0.8906,1.6431)	0.1398 (-0.0788,0.3584) 0.2185
Severe	n (%)	2 (6.7)	4 (12.9)	2.0741 (0.3505,12.2719)	1.9355 (0.3825,9.7944)	0.0624 (-0.0856,0.2103) 0.4174
Non-severe	n (%)	18 (60.0)	21 (67.7)	1.4000 (0.4904, 3.9971)	1.1290 (0.7721,1.6509)	0.0774 (-0.1630,0.3179) 0.5324

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events. For maximum severity, subject incidence rates are reported; therefore a subject contributes only once to each summary for their highest severity.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding 95% CIs were calculated using PROC FREQ. p-value was calculated using PROC FREQ by Fisher's exact test method.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Morb_11

Subjects Gaining >=15 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Number of Subjects, n/N1 (%) [1]	4/ 12 (33.3)	0/ 14
≥ 80 years	Number of Subjects, n/N1 (%) [1]	1/ 12 (8.3)	2/ 12 (16.7)
< 80 years	Number of Subjects, n/N (%) [1]	4/ 17 (23.5)	0/ 17
≥ 80 years	Number of Subjects, n/N (%) [1]	1/ 13 (7.7)	2/ 14 (14.3)

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_11

DATE: 31MAY2024 9:41

Table Morb_12

Subjects Gaining >=10 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Number of Subjects, n/N1 (%) [1]	5/ 12 (41.7)	1/ 14 (7.1)
≥ 80 years	Number of Subjects, n/N1 (%) [1]	4/ 12 (33.3)	2/ 12 (16.7)
< 80 years	Number of Subjects, n/N (%) [1]	5/ 17 (29.4)	1/ 17 (5.9)
≥ 80 years	Number of Subjects, n/N (%) [1]	4/ 13 (30.8)	2/ 14 (14.3)

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_12

DATE: 31MAY2024 9:44

Table Morb_13

Subjects Gaining >=5 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Number of Subjects, n/N1 (%) [1]	5/ 12 (41.7)	8/ 14 (57.1)
	Odds Ratio [2]	1.8667	
	95% CI	(0.3064, 11.7110)	
	Relative Risk [2]	1.3714	
	95% CI	(0.6056, 3.7006)	
	Absolute Risk Reduction [2]	0.1548	
	95% CI	(-0.2460, 0.5194)	
	p-value [3]	0.6951	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_13

DATE: 11JUN2024 13:32

Table Morb_13

Subjects Gaining >=5 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	Number of Subjects, n/N1 (%) [1]	6/ 12 (50.0)	3/ 12 (25.0)
	Odds Ratio [2]	0.3333	
	95% CI	(0.0398, 2.4538)	
	Relative Risk [2]	0.5000	
	95% CI	(0.0697, 1.5270)	
	Absolute Risk Reduction [2]	-0.2500	
	95% CI	(-0.6049, 0.1570)	
	p-value [3]	0.4003	
Interaction	p-value [4]	0.1476	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_13

DATE: 11JUN2024 13:32

Table Morb_13

Subjects Gaining >=5 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Number of Subjects, n/N (%) [1]	5/ 17 (29.4)	8/ 17 (47.1)
	Odds Ratio [2]	2.1333	
	95% CI	(0.4248, 11.2203)	
	Relative Risk [2]	1.6000	
	95% CI	(0.6525, 4.7564)	
	Absolute Risk Reduction [2]	0.1765	
	95% CI	(-0.1620, 0.4890)	
	p-value [3]	0.4813	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_13

DATE: 11JUN2024 13:32

Table Morb_13

Subjects Gaining >=5 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	Number of Subjects, n/N (%) [1]	6/ 13 (46.2)	3/ 14 (21.4)
	Odds Ratio [2]	0.3182	
	95% CI	(0.0399, 2.1963)	
	Relative Risk [2]	0.4643	
	95% CI	(0.0645, 1.4840)	
	Absolute Risk Reduction [2]	-0.2473	
	95% CI	(-0.5810, 0.1264)	
	p-value [3]	0.2365	
Interaction	p-value [4]	0.0934	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_13

DATE: 11JUN2024 13:32

Table Morb_14

Subjects Loosing < 15 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Number of Subjects, n/N1 (%) [1]	10/ 12 (83.3)	12/ 14 (85.7)
	Odds Ratio [2]	1.2000	
	95% CI	(0.0738, 19.2708)	
	Relative Risk [2]	1.0286	
	95% CI	(0.6521, 1.6375)	
	Absolute Risk Reduction [2]	0.0238	
	95% CI	(-0.2858, 0.3566)	
	p-value [3]	>0.9999	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_14

DATE: 11JUN2024 14:10

Table Morb_14

Subjects Loosing < 15 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	Number of Subjects, n/N1 (%) [1]	10/ 12 (83.3)	11/ 12 (91.7)
	Odds Ratio [2] 95% CI	2.2000 (0.0967, 141.3949)	
	Relative Risk [2] 95% CI	1.1000 (0.7304, 1.7319)	
	Absolute Risk Reduction [2] 95% CI	0.0833 (-0.2498, 0.4176)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.7694	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_14

Subjects Loosing < 15 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Number of Subjects, n/N (%) [1]	10/ 17 (58.8)	12/ 17 (70.6)
	Odds Ratio [2]	1.6800	
	95% CI	(0.3285, 8.9389)	
	Relative Risk [2]	1.2000	
	95% CI	(0.6980, 2.2423)	
	Absolute Risk Reduction [2]	0.1176	
	95% CI	(-0.2136, 0.4343)	
	p-value [3]	0.7207	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_14

DATE: 11JUN2024 14:10

Table Morb_14

Subjects Loosing < 15 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	Number of Subjects, n/N (%) [1]	10/ 13 (76.9)	11/ 14 (78.6)
	Odds Ratio [2]	1.1000	
	95% CI	(0.1179, 10.2092)	
	Relative Risk [2]	1.0214	
	95% CI	(0.6303, 1.6959)	
	Absolute Risk Reduction [2]	0.0165	
	95% CI	(-0.3167, 0.3628)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.6326	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_14

DATE: 11JUN2024 14:10

Table Morb_15
BCVA Change from Baseline - Trimmed Means Fixed Approach by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	BCVA Score Change from Baseline to 11 Months [1]	n	10	12
		Mean (SD)	7.6 (10.42)	3.7 (7.35)
		Median	7.0	6.5
		Min, Max	-5, 23	-14, 10
	LS Means (Q1, Q3) [2]		8.045 (6.552, 9.741)	8.113 (6.633, 9.794)
	(95% CI)		(2.844, 12.192)	(2.835, 12.223)
	LS Means Difference			0.068
	(95% CI)			(-9.087, 9.199)
≥ 80 years	BCVA Score Change from Baseline to 11 Months [1]	n	10	11
		Mean (SD)	8.3 (8.60)	2.7 (9.63)
		Median	8.0	3.0
		Min, Max	-2, 27	-10, 20
	LS Means (Q1, Q3) [2]		9.302 (7.787, 10.951)	9.932 (8.505, 11.478)
	(95% CI)		(4.480, 13.521)	(5.396, 13.893)
	LS Means Difference			0.630
	(95% CI)			(-8.013, 9.245)
< 80 years	p-value			0.6210
	Corrected Hedges' G (95% CI)			0.8243 (-0.0523, 1.7009)
≥ 80 years	p-value			0.7710
	Corrected Hedges' G (95% CI)			8.3172 (5.5606, 11.0738)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means fixed approach compares the 50% best (> median) observations in each treatment arm. Those observations with missing data at 11 months had values worse than the median imputed to calculate the adjusted median in which the best 50% were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by taking the 2.5 and 97.5 percentiles from the same permutation distribution. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 2250.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] Q1 = 25th percentile, Q3 = 75th percentile.

Reference Listing: 16.2.6.1

Table Morb_16
BCVA Change from Baseline - Trimmed Means Adaptive Approach by Age Group in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	BCVA Score Change from Baseline to 11 Months [1]	n	10	12
		Mean (SD)	7.6 (10.42)	3.7 (7.35)
		Median	7.0	6.5
		Min, Max	-5, 23	-14, 10
	LS Means (Q1, Q3) [2]		5.617 (4.281, 6.976)	6.220 (4.503, 7.863)
	(95% CI)		(1.667, 9.468)	(1.643, 11.058)
	LS Means Difference			0.603
	(95% CI)			(-7.474, 8.847)
≥ 80 years	p-value			0.7258
	Corrected Hedges' G (95% CI)			7.6857 (5.1803, 10.1910)
	BCVA Score Change from Baseline to 11 Months [1]	n	10	11
		Mean (SD)	8.3 (8.60)	2.7 (9.63)
		Median	8.0	3.0
		Min, Max	-2, 27	-10, 20
	LS Means (Q1, Q3) [2]		5.596 (4.197, 6.957)	6.582 (5.061, 8.135)
	(95% CI)		(1.680, 9.646)	(2.106, 10.960)
	LS Means Difference			0.986
	(95% CI)			(-6.859, 8.758)
	p-value			0.8680
	Corrected Hedges' G (95% CI)			13.5113 (9.1695, 17.8532)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means adaptive approach assigns a percentile floor in the treatment arm based on the greatest proportion of dropouts observed between the two arms. Those observations with missing data at 11 months had values worse than the percentile floor imputed to calculate the adjusted floor in which the best observations were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by taking the 2.5 and 97.5 percentiles from the same permutation distribution. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 2830.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] Q1 = 25th percentile, Q3 = 75th percentile.

Reference Listing: 16.2.6.1

Table Morb_17

BCVA Change from Baseline - Analysis of Covariance by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	BCVA Score Change from Baseline to 11 Months [1]	n	10	12
		Mean (SD)	7.6 (10.42)	3.7 (7.35)
		Median	7.0	6.5
		Min, Max	-5, 23	-14, 10
	LS Means (SE)		8.095 (2.8141)	3.254 (2.5639)
	(95% CI)		(2.205, 13.985)	(-2.112, 8.621)
	LS Means Difference (SE)			-4.840 (3.8474)
	(95% CI)			(-12.893, 3.212)
≥ 80 years	BCVA Score Change from Baseline to 11 Months [1]	n	10	11
		Mean (SD)	8.3 (8.60)	2.7 (9.63)
		Median	8.0	3.0
		Min, Max	-2, 27	-10, 20
	LS Means (SE)		8.075 (2.6826)	2.932 (2.5575)
	(95% CI)		(2.439, 13.711)	(-2.442, 8.305)
	LS Means Difference (SE)			-5.144 (3.7093)
	(95% CI)			(-12.937, 2.650)
	p-value [2]			0.2236
	Corrected Hedges' G (95% CI)			-0.5238 (-1.3783, 0.3307)
	p-value [2]			0.1825
	Corrected Hedges' G (95% CI)			-0.5821 (-1.4579, 0.2937)

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_17

DATE: 16MAY2024 6:57

Table Morb_18

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter [1]	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	BCVA Score Change from Baseline to 11 Months [2]	n	10	12
		Mean (SD)	7.6 (10.42)	3.7 (7.35)
		Median	7.0	6.5
		Min, Max	-5, 23	-14, 10
		LS Means (SE)	7.737 (3.4083)	2.205 (3.3722)
		(95% CI)	(1.049, 14.426)	(-4.412, 8.822)
		LS Means Difference (SE)		-5.532 (4.9684)
		(95% CI)		(-15.284, 4.220)
	p-value [3]			0.2658
	Corrected Hedges' G (95% CI)			-0.4716 (-1.3233, 0.3800)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_18

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Table Morb_18

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter [1]	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	BCVA Score Change from Baseline to 11 Months [2]	n	10	11
		Mean (SD)	8.3 (8.60)	2.7 (9.63)
		Median	8.0	3.0
		Min, Max	-2, 27	-10, 20
	LS Means (SE)		7.480 (3.4500)	3.173 (3.2019)
	(95% CI)		(0.709, 14.251)	(-3.109, 9.455)
	LS Means Difference (SE)			-4.307 (4.5746)
	(95% CI)			(-13.281, 4.667)
	p-value [3]			0.3466
	Corrected Hedges' G (95% CI)			-0.3844 (-1.2493, 0.4805)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_18

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Table Morb_19

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Day 30	BCVA Score Change from Baseline	n	17	16
			Mean (SD)	5.3 (7.03)	2.3 (6.05)
			Median	6.0	2.5
			Min, Max	-9, 16	-11, 18
		LS Means (SE) [1]		5.294 (1.6959)	2.313 (1.7480)
		(95% CI)		(1.855, 8.733)	(-1.232, 5.857)
		LS Means Difference (SE)			-2.982 (2.4355)
		(95% CI)			(-7.921, 1.957)
< 80 years	Day 60	BCVA Score Change from Baseline	n	16	15
			Mean (SD)	5.9 (7.51)	2.3 (5.37)
			Median	6.5	2.0
			Min, Max	-8, 20	-9, 14
		LS Means (SE) [1]		6.030 (1.6848)	2.664 (1.7374)
		(95% CI)		(2.606, 9.455)	(-0.868, 6.195)
		LS Means Difference (SE)			-3.367 (2.4202)
		(95% CI)			(-8.286, 1.553)
		p-value			0.2288
		Corrected Hedges' G (95% CI)			-0.4160 (-1.1064, 0.2744)
		p-value			0.1733
		Corrected Hedges' G (95% CI)			-0.4869 (-1.2022, 0.2284)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_19

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Table Morb_19

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Day 90	BCVA Score Change from Baseline	n	16	15
			Mean (SD)	6.3 (8.74)	3.7 (8.70)
			Median	8.0	5.0
			Min, Max	-14, 17	-24, 14
		LS Means (SE) [1]		6.341 (2.0017)	4.056 (2.0653)
		(95% CI)		(2.328, 10.353)	(-0.084, 8.196)
		LS Means Difference (SE)			-2.285 (2.8761)
< 80 years	Day 120				(-8.050, 3.481)
		p-value			0.4305
		Corrected Hedges' G (95% CI)			-0.2780 (-0.9860, 0.4300)
		BCVA Score Change from Baseline	n	15	14
			Mean (SD)	7.1 (10.34)	3.1 (7.15)
			Median	11.0	4.5
			Min, Max	-13, 18	-11, 14
< 80 years	Day 120	LS Means (SE) [1]		6.100 (2.2220)	1.898 (2.2955)
		(95% CI)		(1.646, 10.554)	(-2.704, 6.499)
		LS Means Difference (SE)			-4.202 (3.1948)
		(95% CI)			(-10.607, 2.202)
		p-value			0.1939
		Corrected Hedges' G (95% CI)			-0.4751 (-1.2142, 0.2641)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_19

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Day 150	BCVA Score Change from Baseline	n	14	12
			Mean (SD)	7.2 (6.84)	1.6 (7.42)
			Median	6.0	4.0
			Min, Max	-3, 21	-12, 11
		LS Means (SE) [1]		6.351 (1.9698)	1.779 (2.0606)
		(95% CI)		(2.392, 10.310)	(-2.361, 5.918)
		LS Means Difference (SE)			-4.573 (2.8507)
		(95% CI)			(-10.300, 1.155)
< 80 years	Day 180		p-value		0.1151
		Corrected Hedges' G (95% CI)			-0.6095 (-1.3993, 0.1803)
		BCVA Score Change from Baseline	n	14	13
			Mean (SD)	8.9 (7.76)	2.5 (6.72)
			Median	7.5	3.0
			Min, Max	-2, 21	-9, 18
		LS Means (SE) [1]		8.103 (1.8393)	1.771 (1.9019)
		(95% CI)		(4.398, 11.808)	(-2.060, 5.601)
		LS Means Difference (SE)			-6.333 (2.6458)
		(95% CI)			(-11.662, -1.004)
		p-value			0.0209
		Corrected Hedges' G (95% CI)			-0.8938 (-1.6878, -0.0999)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_19

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Table Morb_19

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Day 210	BCVA Score Change from Baseline	n	12	13
			Mean (SD)	8.0 (8.09)	2.1 (6.37)
			Median	9.0	3.0
			Min, Max	-6, 19	-10, 10
		LS Means (SE) [1]		7.265 (1.9763)	1.442 (1.9909)
		(95% CI)		(3.291, 11.238)	(-2.564, 5.447)
		LS Means Difference (SE)			-5.823 (2.8053)
		(95% CI)			(-11.465, -0.181)
< 80 years	Day 240	BCVA Score Change from Baseline	n	10	13
			Mean (SD)	7.9 (8.13)	3.2 (5.43)
			Median	11.5	3.0
			Min, Max	-5, 17	-7, 11
		LS Means (SE) [1]		6.296 (1.7864)	2.643 (1.7569)
		(95% CI)		(2.687, 9.904)	(-0.917, 6.203)
		LS Means Difference (SE)			-3.652 (2.5056)
		(95% CI)			(-8.721, 1.416)
< 80 years	Day 240	p-value			0.0434
		Corrected Hedges' G (95% CI)			-0.8020 (-1.6196, 0.0156)
< 80 years	Day 240	BCVA Score Change from Baseline	n	10	13
			Mean (SD)	7.9 (8.13)	3.2 (5.43)
			Median	11.5	3.0
			Min, Max	-5, 17	-7, 11
		LS Means (SE) [1]		6.296 (1.7864)	2.643 (1.7569)
		(95% CI)		(2.687, 9.904)	(-0.917, 6.203)
		LS Means Difference (SE)			-3.652 (2.5056)
		(95% CI)			(-8.721, 1.416)
< 80 years	Day 240	p-value			0.1529
		Corrected Hedges' G (95% CI)			-0.5818 (-1.4245, 0.2608)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_19

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Table Morb_19

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Day 270	BCVA Score Change from Baseline	n	10	12
			Mean (SD)	7.1 (10.62)	1.8 (6.98)
			Median	11.0	2.5
			Min, Max	-13, 20	-10, 10
		LS Means (SE) [1]		5.520 (2.2812)	0.778 (2.1749)
		(95% CI)		(0.934, 10.105)	(-3.593, 5.149)
		LS Means Difference (SE)			-4.742 (3.1518)
		(95% CI)			(-11.076, 1.593)
< 80 years	Day 300	BCVA Score Change from Baseline	n	10	11
			Mean (SD)	8.3 (9.82)	3.4 (5.46)
			Median	9.5	4.0
			Min, Max	-5, 24	-7, 12
		LS Means (SE) [1]		6.848 (2.1481)	3.567 (2.0872)
		(95% CI)		(2.516, 11.179)	(-0.639, 7.774)
		LS Means Difference (SE)			-3.280 (2.9951)
		(95% CI)			(-9.317, 2.757)
< 80 years	Day 300	p-value			0.1389
		Corrected Hedges' G (95% CI)			-0.6171 (-1.4775, 0.2433)
< 80 years	Day 300	BCVA Score Change from Baseline	n	10	11
			Mean (SD)	8.3 (9.82)	3.4 (5.46)
			Median	9.5	4.0
			Min, Max	-5, 24	-7, 12
		LS Means (SE) [1]		6.848 (2.1481)	3.567 (2.0872)
		(95% CI)		(2.516, 11.179)	(-0.639, 7.774)
		LS Means Difference (SE)			-3.280 (2.9951)
		(95% CI)			(-9.317, 2.757)
< 80 years	Day 300	p-value			0.2794
		Corrected Hedges' G (95% CI)			-0.4590 (-1.3275, 0.4095)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_19

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Table Morb_19

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Day 330	BCVA Score Change from Baseline	n	10	12
			Mean (SD)	7.6 (10.42)	3.7 (7.35)
			Median	7.0	6.5
			Min, Max	-5, 23	-14, 10
		LS Means (SE) [1] (95% CI)		6.182 (2.4931)	3.219 (2.3653)
				(1.135, 11.229)	(-1.559, 7.997)
			LS Means Difference (SE) (95% CI)		-2.963 (3.4366)
			p-value		0.3938
< 80 years	Day 365	BCVA Score Change from Baseline	Corrected Hedges' G (95% CI)		-0.3539 (-1.2001, 0.4924)
			n		12
			Mean (SD)		0.7 (8.54)
			Median		2.0
			Min, Max		-12, 10

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_19

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Table Morb_19

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	Day 30	BCVA Score Change from Baseline	n	12	12
			Mean (SD)	5.3 (8.04)	2.7 (7.55)
			Median	3.0	2.0
			Min, Max	-3, 24	-5, 22
		LS Means (SE) [1]		5.250 (2.7075)	2.667 (2.7075)
		(95% CI)		(-0.221, 10.721)	(-2.805, 8.138)
		LS Means Difference (SE)			-2.583 (3.8290)
		(95% CI)			(-10.321, 5.154)
≥ 80 years	Day 60	BCVA Score Change from Baseline	n	12	12
			Mean (SD)	4.9 (8.28)	2.7 (7.06)
			Median	7.0	0.5
			Min, Max	-10, 20	-10, 13
		LS Means (SE) [1]		4.917 (2.3559)	2.667 (2.3559)
		(95% CI)		(0.149, 9.684)	(-2.101, 7.434)
		LS Means Difference (SE)			-2.250 (3.3318)
		(95% CI)			(-8.992, 4.492)
		p-value			0.5037
		Corrected Hedges' G (95% CI)			-0.2659 (-1.0699, 0.5380)
		p-value			0.5035
		Corrected Hedges' G (95% CI)			-0.2662 (-1.0701, 0.5378)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_19

DATE: 16MAY2024 8:58

Table Morb_19

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	Day 90	BCVA Score Change from Baseline	n	12	12
			Mean (SD)	7.0 (7.17)	4.2 (4.97)
			Median	7.5	5.0
			Min, Max	-4, 20	-6, 12
		LS Means (SE) [1] (95% CI)		7.000 (1.8036) (3.267, 10.733)	4.167 (1.8036) (0.433, 7.900)
		LS Means Difference (SE) (95% CI)			-2.833 (2.5507) (-8.113, 2.446)
		p-value			0.2783
		Corrected Hedges' G (95% CI)			-0.4378 (-1.2482, 0.3725)
≥ 80 years	Day 120	BCVA Score Change from Baseline	n	12	12
			Mean (SD)	6.3 (9.64)	1.1 (6.39)
			Median	5.5	1.0
			Min, Max	-6, 29	-9, 13
		LS Means (SE) [1] (95% CI)		6.333 (2.4677) (1.322, 11.345)	1.083 (2.4677) (-3.928, 6.095)
		LS Means Difference (SE) (95% CI)			-5.250 (3.4898) (-12.338, 1.838)
		p-value			0.1416
		Corrected Hedges' G (95% CI)			-0.5930 (-1.4118, 0.2258)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_19

DATE: 16MAY2024 8:58

Table Morb_19

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	Day 150	BCVA Score Change from Baseline	n	12	12
			Mean (SD)	3.8 (7.58)	2.6 (8.41)
			Median	2.0	1.0
			Min, Max	-5, 24	-9, 14
			LS Means (SE) [1]	3.750 (2.8593)	2.583 (2.8593)
			(95% CI)	(-2.035, 9.535)	(-3.202, 8.368)
			LS Means Difference (SE)		-1.167 (4.0437)
			(95% CI)		(-9.348, 7.014)
≥ 80 years	Day 180	BCVA Score Change from Baseline	p-value		0.7745
			Corrected Hedges' G (95% CI)		-0.1137 (-0.9146, 0.6871)
			n	12	12
			Mean (SD)	5.3 (9.40)	2.8 (9.28)
			Median	5.5	4.0
			Min, Max	-8, 27	-10, 16
			LS Means (SE) [1]	5.333 (2.7723)	2.833 (2.7723)
			(95% CI)	(-0.264, 10.931)	(-2.764, 8.431)
			LS Means Difference (SE)		-2.500 (3.9207)
			(95% CI)		(-10.416, 5.416)
			p-value		0.5272
			Corrected Hedges' G (95% CI)		-0.2513 (-1.0549, 0.5522)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_19

DATE: 16MAY2024 8:58

Table Morb_19

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	Day 210	BCVA Score Change from Baseline	n	12	11
			Mean (SD)	4.3 (12.71)	3.8 (8.78)
			Median	4.5	8.0
			Min, Max	-22, 33	-11, 14
		LS Means (SE) [1]		4.333 (2.8574)	4.136 (2.8957)
		(95% CI)		(-1.427, 10.094)	(-1.699, 9.971)
		LS Means Difference (SE)			-0.197 (4.0682)
		(95% CI)			(-8.397, 8.002)
≥ 80 years	Day 240		p-value		0.9616
		Corrected Hedges' G (95% CI)			-0.0195 (-0.8376, 0.7987)
		BCVA Score Change from Baseline	n	11	10
			Mean (SD)	8.3 (11.21)	1.1 (8.24)
			Median	9.0	1.0
			Min, Max	-3, 38	-10, 12
		LS Means (SE) [1]		6.415 (2.6881)	1.912 (2.7315)
		(95% CI)		(0.997, 11.833)	(-3.591, 7.415)
		LS Means Difference (SE)			-4.503 (3.8323)
		(95% CI)			(-12.226, 3.219)
		p-value			0.2462
		Corrected Hedges' G (95% CI)			-0.4921 (-1.3624, 0.3782)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_19

DATE: 16MAY2024 8:58

Table Morb_19

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	Day 270	BCVA Score Change from Baseline	n	10	11
			Mean (SD)	6.3 (14.35)	3.1 (8.99)
			Median	4.5	0.0
			Min, Max	-16, 38	-13, 14
			LS Means (SE) [1]	4.837 (3.3112)	3.446 (3.2911)
			(95% CI)	(-1.845, 11.519)	(-3.199, 10.092)
			LS Means Difference (SE)		-1.391 (4.6685)
			(95% CI)		(-10.815, 8.033)
≥ 80 years	Day 300	BCVA Score Change from Baseline	p-value		0.7672
			Corrected Hedges' G (95% CI)		-0.1247 (-0.9820, 0.7326)
			n	10	11
			Mean (SD)	6.3 (10.86)	2.1 (8.51)
			Median	10.0	3.0
			Min, Max	-12, 25	-12, 17
			LS Means (SE) [1]	3.434 (2.9652)	2.476 (2.9270)
			(95% CI)	(-2.550, 9.419)	(-3.435, 8.386)
			LS Means Difference (SE)		-0.959 (4.1665)
			(95% CI)		(-9.369, 7.452)
			p-value		0.8191
			Corrected Hedges' G (95% CI)		-0.0963 (-0.9533, 0.7606)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_19

DATE: 16MAY2024 8:58

Table Morb_19

BCVA Change from Baseline over Time - Repeated Measures by Age Group in NORSE-1 Study
 (ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	Day 330	BCVA Score Change from Baseline	n	10	11
			Mean (SD)	8.3 (8.60)	2.7 (9.63)
			Median	8.0	3.0
			Min, Max	-2, 27	-10, 20
			LS Means (SE) [1] (95% CI)	6.040 (2.9273) (0.114, 11.966)	3.126 (2.8635) (-2.673, 8.925)
			LS Means Difference (SE) (95% CI)		-2.914 (4.0949) (-11.206, 5.377)
			p-value		0.4810
≥ 80 years	Day 365	BCVA Score Change from Baseline	Corrected Hedges' G (95% CI)		-0.2981 (-1.1596, 0.5634)
			n		11
			Mean (SD)		3.3 (8.84)
			Median		2.0
			Min, Max		-11, 20

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_19

DATE: 16MAY2024 8:58

Table Morb_20

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Age Group in
NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Number of Subjects, n/N1 (%) [1]	3/ 12 (25.0)	3/ 14 (21.4)
≥ 80 years	Number of Subjects, n/N1 (%) [1]	2/ 12 (16.7)	1/ 12 (8.3)
< 80 years	Number of Subjects, n/N (%) [1]	3/ 17 (17.6)	3/ 17 (17.6)
≥ 80 years	Number of Subjects, n/N (%) [1]	2/ 13 (15.4)	1/ 14 (7.1)

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.
20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_20

DATE: 31MAY2024 9:53

Table Morb_21

Subjects Gaining >=15 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Number of Subjects, n/N1 (%) [1]	3/ 12 (25.0)	1/ 8 (12.5)
Female	Number of Subjects, n/N1 (%) [1]	2/ 12 (16.7)	1/ 18 (5.6)
Male	Number of Subjects, n/N (%) [1]	3/ 15 (20.0)	1/ 9 (11.1)
Female	Number of Subjects, n/N (%) [1]	2/ 15 (13.3)	1/ 22 (4.5)

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_21

DATE: 31MAY2024 10:24

Table Morb_22

Subjects Gaining >=10 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Number of Subjects, n/N1 (%) [1]	5/ 12 (41.7)	2/ 8 (25.0)
Female	Number of Subjects, n/N1 (%) [1]	4/ 12 (33.3)	1/ 18 (5.6)
Male	Number of Subjects, n/N (%) [1]	5/ 15 (33.3)	2/ 9 (22.2)
Female	Number of Subjects, n/N (%) [1]	4/ 15 (26.7)	1/ 22 (4.5)

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_22

DATE: 31MAY2024 10:29

Table Morb_23

Subjects Gaining >=5 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Number of Subjects, n/N1 (%) [1]	5/ 12 (41.7)	4/ 8 (50.0)
	Odds Ratio [2]	1.4000	
	95% CI	(0.1639, 11.9108)	
	Relative Risk [2]	1.2000	
	95% CI	(0.3813, 3.6743)	
	Absolute Risk Reduction [2]	0.0833	
	95% CI	(-0.3618, 0.5150)	
	p-value [3]	>0.9999	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_23

DATE: 11JUN2024 14:13

Table Morb_23

Subjects Gaining >=5 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	Number of Subjects, n/N1 (%) [1]	6/ 12 (50.0)	7/ 18 (38.9)
	Odds Ratio [2]	0.6364	
	95% CI	(0.1145, 3.5406)	
	Relative Risk [2]	0.7778	
	95% CI	(0.3263, 2.0312)	
	Absolute Risk Reduction [2]	-0.1111	
	95% CI	(-0.4644, 0.2543)	
	p-value [3]	0.7106	
Interaction	p-value [4]	0.4861	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_23

Subjects Gaining >=5 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Number of Subjects, n/N (%) [1]	5/ 15 (33.3)	4/ 9 (44.4)
	Odds Ratio [2]	1.6000	
	95% CI	(0.2093, 11.7479)	
	Relative Risk [2]	1.3333	
	95% CI	(0.3999, 4.4284)	
	Absolute Risk Reduction [2]	0.1111	
	95% CI	(-0.2898, 0.5113)	
	p-value [3]	0.6785	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_23

DATE: 11JUN2024 14:13

Table Morb_23

Subjects Gaining >=5 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	Number of Subjects, n/N (%) [1]	6/ 15 (40.0)	7/ 22 (31.8)
	Odds Ratio [2]	0.7000	
	95% CI	(0.1457, 3.4437)	
	Relative Risk [2]	0.7955	
	95% CI	(0.3101, 2.1520)	
	Absolute Risk Reduction [2]	-0.0818	
	95% CI	(-0.4089, 0.2336)	
	p-value [3]	0.7304	
Interaction	p-value [4]	0.4641	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

Table Morb_24

Subjects Loosing < 15 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Number of Subjects, n/N1 (%) [1]	9/ 12 (75.0)	8/ 8 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	1.3333 (0.8544, 2.3357)	
	Absolute Risk Reduction [2] 95% CI	0.2500 (-0.1368, 0.5748)	
	p-value [3]	0.2421	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_24

DATE: 18JUN2024 9:34

Table Morb_24

Subjects Loosing < 15 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	Number of Subjects, n/N1 (%) [1]	11/ 12 (91.7)	15/ 18 (83.3)
	Odds Ratio [2]	0.4545	
	95% CI	(0.0079, 6.7406)	
	Relative Risk [2]	0.9091	
	95% CI	(0.6369, 1.3817)	
	Absolute Risk Reduction [2]	-0.0833	
	95% CI	(-0.3572, 0.2383)	
	p-value [3]	0.6315	
Interaction	p-value [4]	0.1653	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_24

DATE: 18JUN2024 9:34

Table Morb_24

Subjects Loosing < 15 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Number of Subjects, n/N (%) [1]	9/ 15 (60.0)	8/ 9 (88.9)
	Odds Ratio [2] 95% CI	5.3333 (0.4466, 275.3884)	
	Relative Risk [2] 95% CI	1.4815 (0.8127, 2.8259)	
	Absolute Risk Reduction [2] 95% CI	0.2889 (-0.1280, 0.6001)	
	p-value [3]	0.1907	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_24

DATE: 18JUN2024 9:34

Table Morb_24

Subjects Loosing < 15 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	Number of Subjects, n/N (%) [1]	11/ 15 (73.3)	15/ 22 (68.2)
	Odds Ratio [2]	0.7792	
	95% CI	(0.1334, 4.0697)	
	Relative Risk [2]	0.9298	
	95% CI	(0.5781, 1.6399)	
	Absolute Risk Reduction [2]	-0.0515	
	95% CI	(-0.3456, 0.2679)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.2361	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_24

DATE: 18JUN2024 9:34

Table Morb_25
BCVA Change from Baseline - Trimmed Means Fixed Approach by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	BCVA Score Change from Baseline to 11 Months [1]	n	9	8
		Mean (SD)	8.7 (11.10)	4.8 (8.56)
		Median	12.0	4.5
		Min, Max	-5, 27	-8, 20
	LS Means (Q1, Q3) [2]		10.471 (8.913, 12.205)	9.764 (7.202, 12.603)
	(95% CI)		(5.348, 14.458)	(1.901, 15.889)
	LS Means Difference			-0.707
	(95% CI)			(-12.341, 10.252)
Female	BCVA Score Change from Baseline to 11 Months [1]	n	11	15
		Mean (SD)	7.4 (8.07)	2.4 (8.39)
		Median	7.0	4.0
		Min, Max	-2, 23	-14, 18
	LS Means (Q1, Q3) [2]		7.680 (6.165, 9.370)	8.323 (7.272, 9.448)
	(95% CI)		(2.832, 11.837)	(5.003, 11.099)
	LS Means Difference			0.643
	(95% CI)			(-6.717, 8.087)
	p-value			0.9151
	Corrected Hedges' G (95% CI)			-7.5736 (-10.4198, -4.7274)
				9.1087 (6.4364, 11.7810)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means fixed approach compares the 50% best (> median) observations in each treatment arm. Those observations with missing data at 11 months had values worse than the median imputed to calculate the adjusted median in which the best 50% were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by taking the 2.5 and 97.5 percentiles from the same permutation distribution. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 2250.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] Q1 = 25th percentile, Q3 = 75th percentile.

Reference Listing: 16.2.6.1

Table Morb_26
BCVA Change from Baseline - Trimmed Means Adaptive Approach by Gender in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	BCVA Score Change from Baseline to 11 Months [1]	n	9	8
		Mean (SD)	8.7 (11.10)	4.8 (8.56)
		Median	12.0	4.5
		Min, Max	-5, 27	-8, 20
	LS Means (Q1, Q3) [2]		6.846 (5.523, 8.087)	7.687 (5.102, 10.324)
	(95% CI)		(3.259, 10.923)	(0.807, 14.482)
	LS Means Difference			0.841
	(95% CI)			(-9.714, 10.832)
Female	BCVA Score Change from Baseline to 11 Months [1]	n	11	15
		Mean (SD)	7.4 (8.07)	2.4 (8.39)
		Median	7.0	4.0
		Min, Max	-2, 23	-14, 18
	LS Means (Q1, Q3) [2]		5.369 (3.556, 7.176)	4.630 (3.556, 5.687)
	(95% CI)		(0.605, 10.174)	(1.678, 7.621)
	LS Means Difference			-0.739
	(95% CI)			(-8.106, 6.630)
	p-value			0.5312
	Corrected Hedges' G (95% CI)			9.7561 (6.1722, 13.3400)
	p-value			0.5312
	Corrected Hedges' G (95% CI)			9.7561 (6.1722, 13.3400)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means adaptive approach assigns a percentile floor in the treatment arm based on the greatest proportion of dropouts observed between the two arms. Those observations with missing data at 11 months had values worse than the percentile floor imputed to calculate the adjusted floor in which the best observations were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by taking the 2.5 and 97.5 percentiles from the same permutation distribution. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 2830.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] Q1 = 25th percentile, Q3 = 75th percentile.

Reference Listing: 16.2.6.1

Table Morb_27

BCVA Change from Baseline - Analysis of Covariance by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	BCVA Score Change from Baseline to 11 Months [1]	n	9	8
		Mean (SD)	8.7 (11.10)	4.8 (8.56)
		Median	12.0	4.5
		Min, Max	-5, 27	-8, 20
	LS Means (SE)		8.571 (3.1247)	4.857 (3.3143)
	(95% CI)		(1.869, 15.273)	(-2.251, 11.966)
	LS Means Difference (SE)			-3.714 (4.5558)
	(95% CI)			(-13.485, 6.057)
Female	BCVA Score Change from Baseline to 11 Months [1]	n	11	15
		Mean (SD)	7.4 (8.07)	2.4 (8.39)
		Median	7.0	4.0
		Min, Max	-2, 23	-14, 18
	LS Means (SE)		7.692 (2.5201)	2.159 (2.1525)
	(95% CI)		(2.479, 12.905)	(-2.294, 6.612)
	LS Means Difference (SE)			-5.533 (3.3412)
	(95% CI)			(-12.445, 1.379)
	p-value [2]			0.4286
	Corrected Hedges' G (95% CI)			-0.3760 (-1.3377, 0.5856)
	p-value [2]			0.1113
	Corrected Hedges' G (95% CI)			-0.6420 (-1.4406, 0.1566)

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_27

DATE: 16MAY2024 7:13

Table Morb_28

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Parameter [1]	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	BCVA Score Change from Baseline to 11 Months [2]	n	9	8
		Mean (SD)	8.7 (11.10)	4.8 (8.56)
		Median	12.0	4.5
		Min, Max	-5, 27	-8, 20
	LS Means (SE)		6.122 (3.6311)	4.991 (4.3805)
	(95% CI)		(-1.002, 13.245)	(-3.597, 13.580)
	LS Means Difference (SE)			-1.130 (5.6853)
	(95% CI)			(-12.279, 10.018)
	p-value [3]			0.8424
	Corrected Hedges' G (95% CI)			-0.0924 (-1.0453, 0.8606)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_28

DATE: 16MAY2024 10:51

Table Morb_28

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Parameter [1]	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	BCVA Score Change from Baseline to 11 Months [2]	n	11	15
		Mean (SD)	7.4 (8.07)	2.4 (8.39)
		Median	7.0	4.0
		Min, Max	-2, 23	-14, 18
		LS Means (SE)	8.631 (3.4404)	2.022 (2.8618)
		(95% CI)	(1.876, 15.385)	(-3.597, 7.641)
		LS Means Difference (SE)		-6.608 (4.4345)
		(95% CI)		(-15.313, 2.096)
	p-value [3]			0.1366
	Corrected Hedges' G (95% CI)			-0.5703 (-1.3647, 0.2240)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_28

DATE: 16MAY2024 10:51

Table Morb_29

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Day 30	BCVA Score Change from Baseline	n	15	8
			Mean (SD)	5.0 (8.47)	2.4 (8.40)
			Median	2.0	-0.5
			Min, Max	-9, 24	-4, 22
			LS Means (SE) [1] (95% CI)	5.000 (2.1814) (0.543, 9.457)	2.375 (2.9870) (-3.729, 8.479)
			LS Means Difference (SE) (95% CI)		-2.625 (3.6987) (-10.183, 4.933)
			p-value		0.4834
			Corrected Hedges' G (95% CI)		-0.2995 (-1.1622, 0.5633)
Male	Day 60	BCVA Score Change from Baseline	n	14	8
			Mean (SD)	5.5 (7.77)	3.0 (5.55)
			Median	7.0	1.0
			Min, Max	-8, 20	-2, 13
			LS Means (SE) [1] (95% CI)	5.601 (1.8452) (1.806, 9.396)	3.000 (2.4973) (-2.141, 8.141)
			LS Means Difference (SE) (95% CI)		-2.601 (3.1051) (-8.991, 3.789)
			p-value		0.4100
			Corrected Hedges' G (95% CI)		-0.3595 (-1.2352, 0.5161)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_29

DATE: 16MAY2024 9:04

Table Morb_29

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Day 90	BCVA Score Change from Baseline	n	14	8
			Mean (SD)	6.1 (9.09)	3.6 (4.47)
			Median	8.0	3.0
		LS Means (SE) [1] (95% CI)	Min, Max	-14, 20	-1, 12
				6.240 (2.0841)	3.625 (2.7994)
				(1.971, 10.509)	(-2.117, 9.367)
					(-2.615 (3.4900)
Male	Day 120	BCVA Score Change from Baseline	p-value		0.4600
			Corrected Hedges' G (95% CI)		-0.3209 (-1.1951, 0.5534)
		LS Means (SE) [1] (95% CI)	n	13	8
			Mean (SD)	6.1 (11.54)	0.4 (4.17)
			Median	8.0	-0.5
			Min, Max	-13, 29	-5, 8
		LS Means Difference (SE) (95% CI)		4.411 (2.9788)	0.375 (3.9122)
				(-1.736, 10.558)	(-7.714, 8.464)
					-4.036 (4.9172)
					(-14.196, 6.123)
		p-value			0.4200
			Corrected Hedges' G (95% CI)		-0.3568 (-1.2446, 0.5311)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_29

DATE: 16MAY2024 9:04

Table Morb_29

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Day 150	BCVA Score Change from Baseline	n	12	8
			Mean (SD)	5.7 (7.97)	2.5 (7.23)
			Median	4.0	2.0
			Min, Max	-5, 24	-9, 14
		LS Means (SE) [1]		4.670 (2.3379)	2.500 (2.9969)
		(95% CI)		(-0.153, 9.493)	(-3.702, 8.702)
		LS Means Difference (SE)			-2.170 (3.8009)
		(95% CI)			(-10.026, 5.686)
Male	Day 180	BCVA Score Change from Baseline	n	12	8
			Mean (SD)	7.8 (9.59)	1.6 (7.37)
			Median	3.5	2.0
			Min, Max	-5, 27	-9, 16
		LS Means (SE) [1]		6.968 (2.4061)	1.625 (3.0326)
		(95% CI)		(2.041, 11.894)	(-4.601, 7.851)
		LS Means Difference (SE)			-5.343 (3.8712)
		(95% CI)			(-13.282, 2.596)
		p-value			0.5735
		Corrected Hedges' G (95% CI)			-0.2520 (-1.1503, 0.6463)
		p-value			0.1788
		Corrected Hedges' G (95% CI)			-0.6070 (-1.5229, 0.3090)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_29

DATE: 16MAY2024 9:04

Table Morb_29

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Day 210	BCVA Score Change from Baseline	n	12	8
			Mean (SD)	7.3 (10.77)	2.9 (7.64)
			Median	5.5	3.5
			Min, Max	-6, 33	-10, 10
		LS Means (SE) [1]		6.548 (2.5672)	2.875 (3.1995)
		(95% CI)		(1.262, 11.834)	(-3.717, 9.467)
		LS Means Difference (SE)			-3.673 (4.1021)
		(95% CI)			(-12.122, 4.776)
Male	Day 240	BCVA Score Change from Baseline	n	10	8
			Mean (SD)	8.6 (12.30)	2.8 (4.98)
			Median	7.0	2.0
			Min, Max	-3, 38	-5, 9
		LS Means (SE) [1]		6.830 (2.6868)	2.750 (3.2070)
		(95% CI)		(1.293, 12.366)	(-3.872, 9.372)
		LS Means Difference (SE)			-4.080 (4.1838)
		(95% CI)			(-12.710, 4.551)
		p-value			0.3791
		Corrected Hedges' G (95% CI)			-0.3929 (-1.2965, 0.5107)
		p-value			0.3392
		Corrected Hedges' G (95% CI)			-0.4439 (-1.3860, 0.4982)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_29

DATE: 16MAY2024 9:04

Table Morb_29

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Day 270	BCVA Score Change from Baseline	n	9	8
			Mean (SD)	5.7 (16.41)	3.3 (7.42)
			Median	4.0	2.5
			Min, Max	-16, 38	-9, 14
			LS Means (SE) [1] (95% CI)	4.213 (3.6463) (-3.346, 11.772)	3.250 (4.1613) (-5.413, 11.913)
			LS Means Difference (SE) (95% CI)		-0.963 (5.5328) (-12.459, 10.533)
			p-value		0.8634
			Corrected Hedges' G (95% CI)		-0.0807 (-1.0335, 0.8721)
Male	Day 300	BCVA Score Change from Baseline	n	9	8
			Mean (SD)	7.1 (11.92)	1.5 (8.19)
			Median	10.0	1.5
			Min, Max	-12, 25	-10, 12
			LS Means (SE) [1] (95% CI)	3.872 (3.3250) (-3.036, 10.781)	1.500 (3.7169) (-6.230, 9.230)
			LS Means Difference (SE) (95% CI)		-2.372 (4.9871) (-12.738, 7.993)
			p-value		0.6392
			Corrected Hedges' G (95% CI)		-0.2201 (-1.1757, 0.7355)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_29

DATE: 16MAY2024 9:04

Table Morb_29

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Day 330	BCVA Score Change from Baseline	n	9	8
			Mean (SD)	8.7 (11.10)	4.8 (8.56)
			Median	12.0	4.5
			Min, Max	-5, 27	-8, 20
		LS Means (SE) [1]		6.028 (3.2225)	4.750 (3.5284)
		(95% CI)		(-0.723, 12.780)	(-2.628, 12.128)
		LS Means Difference (SE)			-1.278 (4.7785)
Male	Day 365	(95% CI)			(-11.276, 8.720)
		p-value			0.7920
		Corrected Hedges' G (95% CI)			-0.1236 (-1.0770, 0.8298)
Male	Day 365	BCVA Score Change from Baseline	n		8
			Mean (SD)		2.4 (9.98)
			Median		2.0
			Min, Max		-11, 20

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_29

DATE: 16MAY2024 9:04

Table Morb_29

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	Day 30	BCVA Score Change from Baseline	n	14	20
			Mean (SD)	5.6 (6.17)	2.5 (6.00)
			Median	6.5	3.0
			Min, Max	-3, 16	-11, 18
			LS Means (SE) [1]	5.571 (2.0470)	2.500 (1.7127)
			(95% CI)	(1.426, 9.717)	(-0.969, 5.969)
			LS Means Difference (SE)		-3.071 (2.6690)
			(95% CI)		(-8.477, 2.334)
Female	Day 60	BCVA Score Change from Baseline	p-value		0.2571
			Corrected Hedges' G (95% CI)		-0.3915 (-1.0811, 0.2981)
			n	14	19
			Mean (SD)	5.5 (7.95)	2.3 (6.38)
			Median	7.0	1.0
			Min, Max	-10, 20	-10, 14
			LS Means (SE) [1]	5.500 (2.0887)	2.515 (1.7603)
			(95% CI)	(1.282, 9.718)	(-1.038, 6.068)
			LS Means Difference (SE)		-2.985 (2.7315)
			(95% CI)		(-8.500, 2.530)
			p-value		0.2808
			Corrected Hedges' G (95% CI)		-0.3766 (-1.0732, 0.3200)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_29

DATE: 16MAY2024 9:04

Table Morb_29

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	Day 90	BCVA Score Change from Baseline	n	14	19
			Mean (SD)	7.0 (7.01)	4.1 (8.13)
			Median	9.0	5.0
			Min, Max	-4, 17	-24, 14
			LS Means (SE) [1] (95% CI)	7.000 (2.1463) (2.682, 11.318)	4.289 (1.8146) (0.640, 7.938)
			LS Means Difference (SE) (95% CI)		-2.711 (2.8106) (-8.364, 2.942)
			p-value		0.3397
			Corrected Hedges' G (95% CI)		-0.3322 (-1.0275, 0.3630)
Female	Day 120	BCVA Score Change from Baseline	n	14	18
			Mean (SD)	7.4 (8.39)	2.9 (7.60)
			Median	10.5	4.5
			Min, Max	-6, 18	-11, 14
			LS Means (SE) [1] (95% CI)	7.429 (2.1145) (3.170, 11.687)	2.101 (1.8034) (-1.527, 5.729)
			LS Means Difference (SE) (95% CI)		-5.328 (2.7791) (-10.922, 0.267)
			p-value		0.0615
			Corrected Hedges' G (95% CI)		-0.6688 (-1.3872, 0.0496)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_29

DATE: 16MAY2024 9:04

Table Morb_29

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	Day 150	BCVA Score Change from Baseline	n	14	16
			Mean (SD)	5.6 (6.90)	1.9 (8.25)
			Median	5.0	3.0
			Min, Max	-4, 21	-12, 12
			LS Means (SE) [1] (95% CI)	5.571 (2.1533) (1.234, 9.909)	1.859 (1.8748) (-1.910, 5.628)
			LS Means Difference (SE) (95% CI)		-3.713 (2.8551) (-9.458, 2.033)
			p-value		0.1999
			Corrected Hedges' G (95% CI)		-0.4653 (-1.1927, 0.2621)
Female	Day 180	BCVA Score Change from Baseline	n	14	17
			Mean (SD)	6.8 (7.94)	3.1 (8.28)
			Median	8.0	4.0
			Min, Max	-8, 20	-10, 18
			LS Means (SE) [1] (95% CI)	6.786 (2.0423) (2.662, 10.910)	2.441 (1.7598) (-1.105, 5.987)
			LS Means Difference (SE) (95% CI)		-4.345 (2.6959) (-9.784, 1.094)
			p-value		0.1144
			Corrected Hedges' G (95% CI)		-0.5694 (-1.2916, 0.1528)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_29

DATE: 16MAY2024 9:04

Table Morb_29

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	Day 210	BCVA Score Change from Baseline	n	12	16
			Mean (SD)	5.0 (10.74)	2.9 (7.61)
			Median	7.5	4.5
			Min, Max	-22, 19	-11, 14
		LS Means (SE) [1]		5.410 (2.3557)	2.337 (2.0201)
		(95% CI)		(0.686, 10.134)	(-1.711, 6.385)
		LS Means Difference (SE)			-3.073 (3.1032)
		(95% CI)			(-9.294, 3.148)
Female	Day 240	BCVA Score Change from Baseline	p-value		0.3264
			Corrected Hedges' G (95% CI)		-0.3677 (-1.1227, 0.3873)
			n	11	15
			Mean (SD)	7.6 (6.96)	2.1 (7.63)
			Median	10.0	3.0
			Min, Max	-5, 17	-10, 12
		LS Means (SE) [1]		7.119 (1.9962)	1.677 (1.6887)
		(95% CI)		(3.077, 11.161)	(-1.739, 5.093)
			LS Means Difference (SE)		-5.442 (2.6147)
			(95% CI)		(-10.734, -0.150)
			p-value		0.0441
			Corrected Hedges' G (95% CI)		-0.8017 (-1.6117, 0.0082)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_29

DATE: 16MAY2024 9:04

Table Morb_29

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	Day 270	BCVA Score Change from Baseline	n	11	15
			Mean (SD)	7.5 (8.36)	1.9 (8.28)
			Median	10.0	2.0
			Min, Max	-5, 20	-13, 14
		LS Means (SE) [1] (95% CI)		7.170 (2.2513) (2.647, 11.693)	1.126 (1.9026) (-2.695, 4.947)
		LS Means Difference (SE) (95% CI)			-6.044 (2.9476) (-11.965, -0.123)
		p-value			0.0456
		Corrected Hedges' G (95% CI)			-0.7899 (-1.5989, 0.0191)
Female	Day 300	BCVA Score Change from Baseline	n	11	14
			Mean (SD)	7.5 (9.02)	3.4 (6.47)
			Median	10.0	3.0
			Min, Max	-5, 24	-12, 17
		LS Means (SE) [1] (95% CI)		7.221 (2.1975) (2.798, 11.644)	3.487 (1.8754) (-0.284, 7.258)
		LS Means Difference (SE) (95% CI)			-3.734 (2.8889) (-9.546, 2.078)
		p-value			0.2025
		Corrected Hedges' G (95% CI)			-0.5060 (-1.3089, 0.2969)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_29

DATE: 16MAY2024 9:04

Table Morb_29

BCVA Change from Baseline over Time - Repeated Measures by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	Day 330	BCVA Score Change from Baseline	n	11	15
			Mean (SD)	7.4 (8.07)	2.4 (8.39)
			Median	7.0	4.0
			Min, Max	-2, 23	-14, 18
			LS Means (SE) [1]	7.175 (2.2616)	1.914 (1.9167)
			(95% CI)	(2.629, 11.721)	(-1.937, 5.765)
			LS Means Difference (SE)		-5.261 (2.9646)
			(95% CI)		(-11.218, 0.697)
Female	Day 365	BCVA Score Change from Baseline	p-value		0.0822
			Corrected Hedges' G (95% CI)		-0.6833 (-1.4846, 0.1180)
			n		15
			Mean (SD)		1.7 (8.12)
			Median		2.0
			Min, Max		-12, 16

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

Table Morb_30

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Gender in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Number of Subjects, n/N1 (%) [1]	3/ 12 (25.0)	0/ 8
Female	Number of Subjects, n/N1 (%) [1]	2/ 12 (16.7)	4/ 18 (22.2)
Male	Number of Subjects, n/N (%) [1]	3/ 15 (20.0)	0/ 9
Female	Number of Subjects, n/N (%) [1]	2/ 15 (13.3)	4/ 22 (18.2)

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing. 20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_30

DATE: 11JUN2024 14:22

Table Morb_31

Subjects Gaining >=15 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Number of Subjects, n/N1 (%) [1]	1/ 10 (10.0)	0/ 20
No	Number of Subjects, n/N1 (%) [1]	4/ 14 (28.6)	2/ 6 (33.3)
Yes	Number of Subjects, n/N (%) [1]	1/ 15 (6.7)	0/ 25
No	Number of Subjects, n/N (%) [1]	4/ 15 (26.7)	2/ 6 (33.3)

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_31

DATE: 31MAY2024 10:36

Table Morb_32

Subjects Gaining ≥ 10 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Number of Subjects, n/N1 (%) [1]	2/ 10 (20.0)	1/ 20 (5.0)
No	Number of Subjects, n/N1 (%) [1]	7/ 14 (50.0)	2/ 6 (33.3)
Yes	Number of Subjects, n/N (%) [1]	2/ 15 (13.3)	1/ 25 (4.0)
No	Number of Subjects, n/N (%) [1]	7/ 15 (46.7)	2/ 6 (33.3)

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_32

DATE: 31MAY2024 10:59

Table Morb_33

Subjects Gaining >=5 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Number of Subjects, n/N1 (%) [1]	3/ 10 (30.0)	8/ 20 (40.0)
	Odds Ratio [2]	1.5556	
	95% CI	(0.2465, 11.9860)	
	Relative Risk [2]	1.3333	
	95% CI	(0.4773, 7.3341)	
	Absolute Risk Reduction [2]	0.1000	
	95% CI	(-0.2972, 0.4340)	
	p-value [3]	0.7020	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_33

DATE: 11JUN2024 14:27

Table Morb_33

Subjects Gaining >=5 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No	Number of Subjects, n/N1 (%) [1]	8/ 14 (57.1)	3/ 6 (50.0)
	Odds Ratio [2]	0.7500	
	95% CI	(0.0728, 7.8672)	
	Relative Risk [2]	0.8750	
	95% CI	(0.1612, 2.1784)	
	Absolute Risk Reduction [2]	-0.0714	
	95% CI	(-0.5345, 0.3933)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.5263	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_33

DATE: 11JUN2024 14:27

Table Morb_33

Subjects Gaining >=5 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Number of Subjects, n/N (%) [1]	3/ 15 (20.0)	8/ 25 (32.0)
	Odds Ratio [2]	1.8824	
	95% CI	(0.3465,13.1067)	
	Relative Risk [2]	1.6000	
	95% CI	(0.5339, 8.8558)	
	Absolute Risk Reduction [2]	0.1200	
	95% CI	(-0.1964, 0.3835)	
	p-value [3]	0.4861	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_33

DATE: 11JUN2024 14:27

Table Morb_33

Subjects Gaining >=5 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No	Number of Subjects, n/N (%) [1]	8/ 15 (53.3)	3/ 6 (50.0)
	Odds Ratio [2]	0.8750	
	95% CI	(0.0867, 8.9018)	
	Relative Risk [2]	0.9375	
	95% CI	(0.1722, 2.3629)	
	Absolute Risk Reduction [2]	-0.0333	
	95% CI	(-0.4955, 0.4345)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.3793	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_33

DATE: 11JUN2024 14:27

Table Morb_34

Subjects Loosing < 15 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Number of Subjects, n/N1 (%) [1]	9/ 10 (90.0)	17/ 20 (85.0)
	Odds Ratio [2]	0.6296	
	95% CI	(0.0108,9.3806)	
	Relative Risk [2]	0.9444	
	95% CI	(0.6782,1.5414)	
	Absolute Risk Reduction [2]	-0.0500	
	95% CI	(-0.3094,0.2973)	
	p-value [3]	>0.9999	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_34

DATE: 18JUN2024 9:49

Table Morb_34

Subjects Loosing < 15 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No	Number of Subjects, n/N1 (%) [1]	11/ 14 (78.6)	6/ 6 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	1.2727 (0.6620, 2.0324)	
	Absolute Risk Reduction [2] 95% CI	0.2143 (-0.2523, 0.5094)	
	p-value [3]	0.5211	
Interaction	p-value [4]	0.3000	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_34

DATE: 18JUN2024 9:49

Table Morb_34

Subjects Loosing < 15 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Number of Subjects, n/N (%) [1]	9/ 15 (60.0)	17/ 25 (68.0)
	Odds Ratio [2] 95% CI	1.4167 (0.2997,6.4653)	
	Relative Risk [2] 95% CI	1.1333 (0.6883,2.1608)	
	Absolute Risk Reduction [2] 95% CI	0.0800 (-0.2247,0.3929)	
	p-value [3]	0.7356	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_34

DATE: 18JUN2024 9:49

Table Morb_34

Subjects Loosing < 15 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No	Number of Subjects, n/N (%) [1]	11/ 15 (73.3)	6/ 6 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	1.3636 (0.7055, 2.2272)	
	Absolute Risk Reduction [2] 95% CI	0.2667 (-0.2136, 0.5548)	
	p-value [3]	0.2807	
Interaction	p-value [4]	0.9075	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_34

DATE: 18JUN2024 9:49

Table Morb_35
BCVA Change from Baseline - Trimmed Means Fixed Approach by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab(N=30)	ONS-5010(N=31)
Yes	BCVA Score Change from Baseline to 11 Months [1]	n	9	17
		Mean (SD)	3.0 (7.71)	1.8 (7.21)
		Median	0.0	4.0
		Min, Max	-5, 17	-14, 10
		LS Means (Q1, Q3) [2]	4.449 (2.975, 6.080)	4.666 (3.748, 5.712)
		(95% CI)	(-0.237, 8.416)	(1.600, 7.165)
		LS Means Difference		0.216
		(95% CI)		(-6.698, 7.339)
		p-value		0.4044
		Corrected Hedges' G (95% CI)		3.3687 (2.1251, 4.6124)
No	BCVA Score Change from Baseline to 11 Months [1]	n	11	6
		Mean (SD)	12.0 (8.76)	7.3 (10.58)
		Median	12.0	6.0
		Min, Max	-1, 27	-8, 20
		LS Means (Q1, Q3) [2]	15.326 (14.383, 16.400)	14.996 (13.369, 17.359)
		(95% CI)	(12.123, 17.495)	(7.086, 19.802)
		LS Means Difference		-0.330
		(95% CI)		(-9.815, 6.916)
		p-value		0.6274
		Corrected Hedges' G (95% CI)		-5.1311 (-7.2028, -3.0595)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means fixed approach compares the 50% best (> median) observations in each treatment arm. Those observations with missing data at 11 months had values worse than the median imputed to calculate the adjusted median in which the best 50% were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by taking the 2.5 and 97.5 percentiles from the same permutation distribution. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 2250.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] Q1 = 25th percentile, Q3 = 75th percentile.

Reference Listing: 16.2.6.1

Table Morb_36
BCVA Change from Baseline - Trimmed Means Adaptive Approach by Prior Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	BCVA Score Change from Baseline to 11 Months [1]	n	9	17
		Mean (SD)	3.0 (7.71)	1.8 (7.21)
		Median	0.0	4.0
		Min, Max	-5, 17	-14, 10
	LS Means (Q1, Q3) [2]		2.531 (1.154, 3.872)	3.210 (1.980, 4.377)
	(95% CI)		(-1.237, 6.413)	(0.177, 6.639)
	LS Means Difference (95% CI)			0.678 (-5.423, 7.035)
	p-value			0.5624
No	BCVA Score Change from Baseline to 11 Months [1]	n	11	6
		Mean (SD)	12.0 (8.76)	7.3 (10.58)
		Median	12.0	6.0
		Min, Max	-1, 27	-8, 20
	LS Means (Q1, Q3) [2]		10.400 (9.472, 11.294)	11.344 (8.969, 13.992)
	(95% CI)		(7.773, 13.342)	(3.758, 17.403)
	LS Means Difference (95% CI)			0.944 (-9.129, 9.400)
	p-value			0.6837
	Corrected Hedges' G (95% CI)			9.9180 (7.0195, 12.8166)
				14.1721 (9.0555, 19.2887)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means adaptive approach assigns a percentile floor in the treatment arm based on the greatest proportion of dropouts observed between the two arms. Those observations with missing data at 11 months had values worse than the percentile floor imputed to calculate the adjusted floor in which the best observations were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by taking the 2.5 and 97.5 percentiles from the same permutation distribution. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 2830.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] Q1 = 25th percentile, Q3 = 75th percentile.

Reference Listing: 16.2.6.1

Table Morb_37

BCVA Change from Baseline - Analysis of Covariance by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	BCVA Score Change from Baseline to 11 Months [1]	n	9	17
		Mean (SD)	3.0 (7.71)	1.8 (7.21)
		Median	0.0	4.0
		Min, Max	-5, 17	-14, 10
	LS Means (SE)		3.500 (2.4276)	1.500 (1.7581)
	(95% CI)		(-1.522, 8.522)	(-2.137, 5.137)
	LS Means Difference (SE)			-2.000 (3.0180)
	(95% CI)			(-8.244, 4.243)
No	BCVA Score Change from Baseline to 11 Months [1]	n	11	6
		Mean (SD)	12.0 (8.76)	7.3 (10.58)
		Median	12.0	6.0
		Min, Max	-1, 27	-8, 20
	LS Means (SE)		11.853 (2.4301)	7.602 (3.2912)
	(95% CI)		(6.641, 17.066)	(0.543, 14.661)
	LS Means Difference (SE)			-4.251 (4.0926)
	(95% CI)			(-13.029, 4.526)
	p-value [2]			0.5140
	Corrected Hedges' G (95% CI)			-0.2668 (-1.0783, 0.5446)
	p-value [2]			0.3165
	Corrected Hedges' G (95% CI)			-0.5006 (-1.5110, 0.5098)

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_37

DATE: 16MAY2024 7:18

Table Morb_38

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter [1]	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	BCVA Score Change from Baseline to 11 Months [2]	n	9	17
		Mean (SD)	3.0 (7.71)	1.8 (7.21)
		Median	0.0	4.0
		Min, Max	-5, 17	-14, 10
	LS Means (SE)		4.884 (3.4759)	1.529 (2.7912)
	(95% CI)		(-1.939, 11.707)	(-3.953, 7.011)
	LS Means Difference (SE)			-3.355 (4.5478)
	(95% CI)			(-12.285, 5.574)
	p-value [3]			0.4609
	Corrected Hedges' G (95% CI)			-0.2911 (-1.1032, 0.5210)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_38

DATE: 15MAY2024 12:45

Table Morb_38

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter [1]	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
No	BCVA Score Change from Baseline to 11 Months [2]	n	11	6
		Mean (SD)	12.0 (8.76)	7.3 (10.58)
		Median	12.0	6.0
		Min, Max	-1, 27	-8, 20
	LS Means (SE)		10.333 (3.3648)	7.366 (4.2169)
	(95% CI)		(3.727, 16.939)	(-0.899, 15.631)
	LS Means Difference (SE)			-2.967 (5.3963)
	(95% CI)			(-13.546, 7.613)
	p-value [3]			0.5825
	Corrected Hedges' G (95% CI)			-0.2586 (-1.2575, 0.7404)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_38

DATE: 15MAY2024 12:45

Table Morb_39

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Day 30	BCVA Score Change from Baseline	n	14	22
			Mean (SD)	2.4 (6.46)	2.7 (7.25)
			Median	1.0	2.0
			Min, Max	-9, 16	-11, 22
		LS Means (SE) [1]		2.357 (2.1459)	2.727 (1.7119)
		(95% CI)		(-1.961, 6.675)	(-0.717, 6.172)
		LS Means Difference (SE)			0.370 (2.7451)
		(95% CI)			(-5.153, 5.894)
Yes	Day 60	BCVA Score Change from Baseline	n	13	21
			Mean (SD)	1.8 (7.38)	2.3 (6.39)
			Median	1.0	0.0
			Min, Max	-10, 15	-10, 14
		LS Means (SE) [1]		2.106 (2.0178)	2.469 (1.6006)
		(95% CI)		(-1.974, 6.187)	(-0.769, 5.706)
		LS Means Difference (SE)			0.362 (2.5755)
		(95% CI)			(-4.847, 5.571)
		p-value			0.8933
		Corrected Hedges' G (95% CI)			0.0451 (-0.6251, 0.7152)
		p-value			0.8888
		Corrected Hedges' G (95% CI)			0.0484 (-0.6434, 0.7402)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_39

DATE: 16MAY2024 9:15

Table Morb_39

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Day 90	BCVA Score Change from Baseline	n	13	21
			Mean (SD)	2.6 (7.92)	3.6 (7.76)
			Median	1.0	5.0
			Min, Max	-14, 16	-24, 14
		LS Means (SE) [1]		2.853 (2.0863)	3.786 (1.6518)
		(95% CI)		(-1.333, 7.039)	(0.470, 7.101)
		LS Means Difference (SE)			0.933 (2.6610)
		(95% CI)			(-4.407, 6.273)
Yes	Day 120	BCVA Score Change from Baseline	n	12	20
			Mean (SD)	4.0 (8.54)	1.8 (6.85)
			Median	2.0	2.5
			Min, Max	-13, 17	-11, 14
		LS Means (SE) [1]		3.178 (2.1723)	0.993 (1.7079)
		(95% CI)		(-1.180, 7.537)	(-2.436, 4.422)
		LS Means Difference (SE)			-2.185 (2.7633)
		(95% CI)			(-7.731, 3.360)
		p-value			0.7272
		Corrected Hedges' G (95% CI)			0.1207 (-0.5717, 0.8130)
		p-value			0.4326
		Corrected Hedges' G (95% CI)			-0.2804 (-0.9996, 0.4387)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_39

DATE: 16MAY2024 9:15

Table Morb_39

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Day 150	BCVA Score Change from Baseline	n	11	18
			Mean (SD)	3.1 (5.17)	0.9 (7.86)
			Median	4.0	1.0
		LS Means (SE) [1] (95% CI)	Min, Max	-4, 12	-12, 11
				2.683 (2.1513)	0.948 (1.6907)
				(-1.638, 7.004)	(-2.450, 4.347)
					(-1.735 (2.7362)
Yes	Day 180	BCVA Score Change from Baseline			(-7.232, 3.763)
			p-value		0.5290
			Corrected Hedges' G (95% CI)		-0.2355 (-0.9882, 0.5172)
		LS Means (SE) [1] (95% CI)	n	11	19
			Mean (SD)	3.8 (6.03)	1.2 (7.60)
			Median	2.0	3.0
			Min, Max	-4, 17	-10, 18
		LS Means (SE) [1] (95% CI)		3.428 (1.9816)	0.579 (1.5490)
				(-0.573, 7.429)	(-2.553, 3.711)
					-2.849 (2.5152)
					(-7.930, 2.232)
		LS Means Difference (SE) (95% CI)	p-value		0.2639
			Corrected Hedges' G (95% CI)		-0.4145 (-1.1648, 0.3359)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_39

DATE: 16MAY2024 9:15

Table Morb_39

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Day 210	BCVA Score Change from Baseline	n	10	18
			Mean (SD)	2.8 (6.94)	2.3 (7.80)
			Median	3.0	4.5
			Min, Max	-6, 17	-11, 12
		LS Means (SE) [1]		3.065 (2.3923)	1.937 (1.8386)
		(95% CI)		(-1.737, 7.866)	(-1.755, 5.630)
		LS Means Difference (SE)			-1.127 (3.0172)
		(95% CI)			(-7.184, 4.929)
Yes	Day 240	BCVA Score Change from Baseline	n	9	17
			Mean (SD)	3.4 (7.47)	1.2 (6.78)
			Median	1.0	2.0
			Min, Max	-5, 16	-10, 12
		LS Means (SE) [1]		3.479 (2.0633)	1.030 (1.5843)
		(95% CI)		(-0.677, 7.636)	(-2.168, 4.228)
		LS Means Difference (SE)			-2.449 (2.6014)
		(95% CI)			(-7.694, 2.795)
		p-value			0.7102
		Corrected Hedges' G (95% CI)			-0.1418 (-0.9158, 0.6322)
		p-value			0.3516
		Corrected Hedges' G (95% CI)			-0.3695 (-1.1841, 0.4451)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_39

DATE: 16MAY2024 9:15

Table Morb_39

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Day 270	BCVA Score Change from Baseline	n	9	18
			Mean (SD)	2.6 (8.97)	0.7 (7.52)
			Median	2.0	0.0
		LS Means (SE) [1] (95% CI)	Min, Max	-13, 14	-13, 13
				2.681 (2.4536)	0.232 (1.8304)
				(-2.240, 7.602)	(-3.442, 3.907)
					-2.449 (3.0611)
Yes	Day 300	BCVA Score Change from Baseline			(-8.590, 3.692)
			p-value		0.4274
			Corrected Hedges' G (95% CI)		-0.3108 (-1.1156, 0.4939)
		LS Means (SE) [1] (95% CI)	n	9	16
			Mean (SD)	1.2 (8.58)	1.4 (6.21)
			Median	1.0	3.0
			Min, Max	-12, 12	-12, 12
		LS Means (SE) [1] (95% CI)		1.420 (2.5322)	1.603 (1.9285)
				(-3.667, 6.506)	(-2.271, 5.478)
					0.184 (3.1830)
					(-6.210, 6.578)
		LS Means Difference (SE) (95% CI)	p-value		0.9542
			Corrected Hedges' G (95% CI)		0.0232 (-0.7935, 0.8399)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.
Reference Listing: 16.2.6.1

Table Morb_39

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Day 330	BCVA Score Change from Baseline	n	9	17
			Mean (SD)	3.0 (7.71)	1.8 (7.21)
			Median	0.0	4.0
			Min, Max	-5, 17	-14, 10
		LS Means (SE) [1]		3.228 (2.2983)	1.503 (1.7453)
		(95% CI)		(-1.390, 7.846)	(-2.008, 5.013)
		LS Means Difference (SE)			-1.725 (2.8859)
		(95% CI)			(-7.526, 4.075)
Yes	Day 365	BCVA Score Change from Baseline	p-value		0.5527
			Corrected Hedges' G (95% CI)		-0.2354 (-1.0461, 0.5753)
			n		17
			Mean (SD)		0.2 (7.69)
			Median		2.0
			Min, Max		-12, 10

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_39

DATE: 16MAY2024 9:15

Table Morb_39

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
No	Day 30	BCVA Score Change from Baseline	n	15	6
			Mean (SD)	8.0 (7.21)	1.5 (3.62)
			Median	8.0	2.0
			Min, Max	-3, 24	-4, 6
		LS Means (SE) [1] (95% CI)		8.000 (2.7504) (2.396, 13.604)	1.500 (4.3488) (-7.361, 10.361)
		LS Means Difference (SE) (95% CI)			-6.500 (5.1456) (-16.985, 3.985)
		p-value			0.2157
No	Day 60	BCVA Score Change from Baseline	n	15	6
			Mean (SD)	8.7 (6.70)	3.2 (5.15)
			Median	8.0	2.5
			Min, Max	-5, 20	-1, 13
		LS Means (SE) [1] (95% CI)		8.667 (2.6277) (3.277, 14.056)	3.167 (4.1548) (-5.355, 11.688)
		LS Means Difference (SE) (95% CI)			-5.500 (4.9160) (-15.583, 4.583)
		p-value			0.2730
		Corrected Hedges' G (95% CI)			-0.5858 (-1.5504, 0.3788)
		Corrected Hedges' G (95% CI)			-0.5188 (-1.4796, 0.4420)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_39

DATE: 16MAY2024 9:15

Table Morb_39

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
No	Day 90	BCVA Score Change from Baseline	n	15	6
			Mean (SD)	10.0 (6.46)	5.0 (4.90)
			Median	11.0	5.5
			Min, Max	-2, 20	-1, 12
		LS Means (SE) [1]		10.000 (2.6770)	5.000 (4.2327)
		(95% CI)		(4.493, 15.507)	(-3.708, 13.708)
		LS Means Difference (SE)			-5.000 (5.0082)
		(95% CI)			(-15.303, 5.303)
No	Day 120	BCVA Score Change from Baseline	n	15	6
			Mean (SD)	9.0 (10.54)	3.3 (6.89)
			Median	11.0	2.5
			Min, Max	-13, 29	-5, 13
		LS Means (SE) [1]		9.000 (2.9479)	3.333 (4.6611)
		(95% CI)		(2.879, 15.121)	(-6.345, 13.012)
		LS Means Difference (SE)			-5.667 (5.5151)
		(95% CI)			(-17.119, 5.785)
		p-value			0.3275
		Corrected Hedges' G (95% CI)			-0.4630 (-1.4209, 0.4950)
		p-value			0.3156
		Corrected Hedges' G (95% CI)			-0.4765 (-1.4351, 0.4821)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_39

DATE: 16MAY2024 9:15

Table Morb_39

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
No	Day 150	BCVA Score Change from Baseline	n	15	6
			Mean (SD)	7.5 (8.15)	5.7 (6.89)
			Median	5.0	5.5
			Min, Max	-5, 24	-4, 14
		LS Means (SE) [1]		7.467 (2.0820)	5.667 (3.2919)
		(95% CI)		(3.062, 11.871)	(-1.298, 12.631)
		LS Means Difference (SE)			-1.800 (3.8950)
		(95% CI)			(-10.040, 6.440)
No	Day 180	BCVA Score Change from Baseline	n	15	6
			Mean (SD)	9.8 (9.44)	7.2 (7.60)
			Median	9.0	6.0
			Min, Max	-8, 27	-2, 16
		LS Means (SE) [1]		9.800 (2.6190)	7.167 (4.1410)
		(95% CI)		(4.350, 15.250)	(-1.451, 15.784)
		LS Means Difference (SE)			-2.633 (4.8997)
		(95% CI)			(-12.830, 7.563)
		p-value			0.6501
		Corrected Hedges' G (95% CI)			-0.2143 (-1.1635, 0.7349)
		p-value			0.5967
		Corrected Hedges' G (95% CI)			-0.2492 (-1.1992, 0.7008)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_39

DATE: 16MAY2024 9:15

Table Morb_39

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
No	Day 210	BCVA Score Change from Baseline	n	14	6
			Mean (SD)	8.6 (12.25)	4.5 (6.66)
			Median	9.5	3.5
			Min, Max	-22, 33	-3, 14
		LS Means (SE) [1]		8.308 (2.9257)	4.500 (4.5881)
		(95% CI)		(2.264, 14.351)	(-4.986, 13.986)
		LS Means Difference (SE)			-3.808 (5.4415)
		(95% CI)			(-15.055, 7.440)
No	Day 240	BCVA Score Change from Baseline	n	12	6
			Mean (SD)	11.6 (9.84)	5.3 (6.02)
			Median	10.5	7.5
			Min, Max	-3, 38	-3, 12
		LS Means (SE) [1]		9.660 (2.7909)	5.333 (4.2849)
		(95% CI)		(3.869, 15.450)	(-3.576, 14.243)
		LS Means Difference (SE)			-4.326 (5.1137)
		(95% CI)			(-14.952, 6.299)
		p-value			0.4910
		Corrected Hedges' G (95% CI)			-0.3307 (-1.2930, 0.6317)
		p-value			0.4069
		Corrected Hedges' G (95% CI)			-0.4148 (-1.4050, 0.5755)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_39

DATE: 16MAY2024 9:15

Table Morb_39

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
No	Day 270	BCVA Score Change from Baseline	n	11	5
			Mean (SD)	10.1 (13.95)	8.6 (6.07)
			Median	12.0	10.0
			Min, Max	-16, 38	0, 14
		LS Means (SE) [1]		8.198 (3.1082)	7.373 (4.7126)
		(95% CI)		(1.717, 14.680)	(-2.463, 17.209)
		LS Means Difference (SE)			-0.825 (5.6453)
No	Day 300	(95% CI)			(-12.604, 10.954)
		p-value			0.8852
		Corrected Hedges' G (95% CI)			-0.0752 (-1.1327, 0.9823)
		BCVA Score Change from Baseline	n	11	6
			Mean (SD)	12.3 (8.70)	6.3 (8.33)
			Median	11.0	6.5
			Min, Max	-2, 25	-7, 17
		LS Means (SE) [1]		8.649 (3.2408)	6.333 (4.7612)
		(95% CI)		(1.801, 15.497)	(-3.735, 16.402)
		LS Means Difference (SE)			-2.315 (5.7595)
		(95% CI)			(-14.491, 9.861)
		p-value			0.6928
		Corrected Hedges' G (95% CI)			-0.1987 (-1.1959, 0.7986)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_39

DATE: 16MAY2024 9:15

Table Morb_39

BCVA Change from Baseline over Time - Repeated Measures by Prior Anti-VEGF Therapy in NORSE-1 Study
 (ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
No	Day 330	BCVA Score Change from Baseline	n	11	6
			Mean (SD)	12.0 (8.76)	7.3 (10.58)
			Median	12.0	6.0
			Min, Max	-1, 27	-8, 20
		LS Means (SE) [1]		9.394 (2.8113)	7.333 (4.1707)
		(95% CI)		(3.610, 15.178)	(-1.254, 15.920)
		LS Means Difference (SE)			-2.061 (5.0297)
		(95% CI)			(-12.413, 8.291)
No	Day 365	BCVA Score Change from Baseline	p-value		0.6855
			Corrected Hedges' G (95% CI)		-0.2031 (-1.2004, 0.7942)
			n		6
			Mean (SD)		6.8 (9.81)
			Median		5.5
			Min, Max		-4, 20

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_39

DATE: 16MAY2024 9:15

Table Morb_40

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Prior Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Number of Subjects, n/N1 (%) [1]	2/ 10 (20.0)	4/ 20 (20.0)
No	Number of Subjects, n/N1 (%) [1]	3/ 14 (21.4)	0/ 6
Yes	Number of Subjects, n/N (%) [1]	2/ 15 (13.3)	4/ 25 (16.0)
No	Number of Subjects, n/N (%) [1]	3/ 15 (20.0)	0/ 6

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing. 20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_40

DATE: 31MAY2024 11:01

Table Morb_41

Subjects Gaining ≥ 15 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Number of Subjects, n/N1 (%) [1]	5/ 17 (29.4)	2/ 13 (15.4)
≥ 68 letters	Number of Subjects, n/N1 (%) [1]	0/ 7	0/ 13
≤ 67 letters	Number of Subjects, n/N (%) [1]	5/ 21 (23.8)	2/ 15 (13.3)
≥ 68 letters	Number of Subjects, n/N (%) [1]	0/ 9	0/ 16

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_41

DATE: 31MAY2024 11:12

Table Morb_42

Subjects Gaining ≥ 10 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Number of Subjects, n/N1 (%) [1]	6/ 17 (35.3)	3/ 13 (23.1)
≥ 68 letters	Number of Subjects, n/N1 (%) [1]	3/ 7 (42.9)	0/ 13
≤ 67 letters	Number of Subjects, n/N (%) [1]	6/ 21 (28.6)	3/ 15 (20.0)
≥ 68 letters	Number of Subjects, n/N (%) [1]	3/ 9 (33.3)	0/ 16

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_42

DATE: 31MAY2024 11:15

Table Morb_43

Subjects Gaining ≥5 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Number of Subjects, n/N1 (%) [1]	8/ 17 (47.1)	5/ 13 (38.5)
	Odds Ratio [2]	0.7031	
	95% CI	(0.1250, 3.8003)	
	Relative Risk [2]	0.8173	
	95% CI	(0.2872, 1.9960)	
	Absolute Risk Reduction [2]	-0.0860	
	95% CI	(-0.4310, 0.2788)	
	p-value [3]	0.7213	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_43

DATE: 11JUN2024 14:32

Table Morb_43

Subjects Gaining >=5 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	Number of Subjects, n/N1 (%) [1]	3/ 7 (42.9)	6/ 13 (46.2)
	Odds Ratio [2] 95% CI	1.1429 (0.1277, 11.1340)	
	Relative Risk [2] 95% CI	1.0769 (0.3810, 7.7431)	
	Absolute Risk Reduction [2] 95% CI	0.0330 (-0.4305, 0.4672)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.6421	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_43

DATE: 11JUN2024 14:32

Table Morb_43

Subjects Gaining ≥ 5 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Number of Subjects, n/N (%) [1]	8/ 21 (38.1)	5/ 15 (33.3)
	Odds Ratio [2]	0.8125	
	95% CI	(0.1575, 3.9512)	
	Relative Risk [2]	0.8750	
	95% CI	(0.2878, 2.1692)	
	Absolute Risk Reduction [2]	-0.0476	
	95% CI	(-0.3584, 0.2837)	
	p-value [3]	>0.9999	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_43

DATE: 11JUN2024 14:32

Table Morb_43

Subjects Gaining >=5 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	Number of Subjects, n/N (%) [1]	3/ 9 (33.3)	6/ 16 (37.5)
	Odds Ratio [2]	1.2000	
	95% CI	(0.1655, 10.2052)	
	Relative Risk [2]	1.1250	
	95% CI	(0.3543, 8.1515)	
	Absolute Risk Reduction [2]	0.0417	
	95% CI	(-0.3703, 0.4103)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.7206	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_43

DATE: 11JUN2024 14:32

Table Morb_44

Subjects Loosing < 15 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Number of Subjects, n/N1 (%) [1]	13/ 17 (76.5)	11/ 13 (84.6)
	Odds Ratio [2]	1.6923	
	95% CI	(0.1933, 21.7382)	
	Relative Risk [2]	1.1065	
	95% CI	(0.7114, 1.7506)	
	Absolute Risk Reduction [2]	0.0814	
	95% CI	(-0.2471, 0.3785)	
	p-value [3]	0.6725	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_44

DATE: 11JUN2024 14:35

Table Morb_44

Subjects Loosing < 15 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	Number of Subjects, n/N1 (%) [1]	7/ 7 (100.0)	12/ 13 (92.3)
	Odds Ratio [2]	0.0000	
	95% CI	(0.0000, 35.2857)	
	Relative Risk [2]	0.9231	
	95% CI	(0.6397, 1.5572)	
	Absolute Risk Reduction [2]	-0.0769	
	95% CI	(-0.3670, 0.3210)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.5099	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_44

DATE: 11JUN2024 14:35

Table Morb_44

Subjects Loosing < 15 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Number of Subjects, n/N (%) [1]	13/ 21 (61.9)	11/ 15 (73.3)
	Odds Ratio [2]	1.6923	
	95% CI	(0.3299, 9.7395)	
	Relative Risk [2]	1.1846	
	95% CI	(0.6944, 1.9786)	
	Absolute Risk Reduction [2]	0.1143	
	95% CI	(-0.2237, 0.4136)	
	p-value [3]	0.7210	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_44

DATE: 11JUN2024 14:35

Table Morb_44

Subjects Loosing < 15 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	Number of Subjects, n/N (%) [1]	7/ 9 (77.8)	12/ 16 (75.0)
	Odds Ratio [2] 95% CI	0.8571 (0.0626, 8.0360)	
	Relative Risk [2] 95% CI	0.9643 (0.5895, 1.8604)	
	Absolute Risk Reduction [2] 95% CI	-0.0278 (-0.3676, 0.3793)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.5351	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_44

DATE: 11JUN2024 14:35

Table Morb_45
BCVA Change from Baseline - Trimmed Means Fixed Approach by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab(N=30)	ONS-5010(N=31)
≤ 67 letters BCVA Score Change from Baseline to 11 Months [1]	n		13	11
	Mean (SD)		9.7 (10.10)	3.2 (11.14)
	Median		9.0	4.0
	Min, Max		-5, 27	-14, 20
	LS Means (Q1, Q3) [2]		10.480 (8.871, 12.311)	10.077 (7.832, 12.552)
	(95% CI)		(5.178, 14.747)	(2.889, 16.053)
	LS Means Difference (95% CI)			-0.402 (-11.698, 10.750)
	p-value			0.7025
	Corrected Hedges' G (95% CI)			-3.8253 (-5.2040, -2.4465)
≥ 68 letters BCVA Score Change from Baseline to 11 Months [1]	n		7	12
	Mean (SD)		4.7 (7.16)	3.3 (5.10)
	Median		0.0	4.5
	Min, Max		-2, 13	-8, 9
	LS Means (Q1, Q3) [2]		6.112 (4.655, 7.704)	6.922 (6.103, 7.826)
	(95% CI)		(1.623, 9.748)	(4.402, 8.983)
	LS Means Difference (95% CI)			0.810 (-5.220, 7.167)
	p-value			0.5748
	Corrected Hedges' G (95% CI)			16.3555 (10.8322, 21.8787)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means fixed approach compares the 50% best (> median) observations in each treatment arm. Those observations with missing data at 11 months had values worse than the median imputed to calculate the adjusted median in which the best 50% were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by taking the 2.5 and 97.5 percentiles from the same permutation distribution. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 2250.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] Q1 = 25th percentile, Q3 = 75th percentile.

Reference Listing: 16.2.6.1

Table Morb_46
BCVA Change from Baseline - Trimmed Means Adaptive Approach by Baseline BCVA Score in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters BCVA Score Change from Baseline to 11 Months [1]	n		13	11
	Mean (SD)		9.7 (10.10)	3.2 (11.14)
	Median		9.0	4.0
	Min, Max		-5, 27	-14, 20
	LS Means (Q1, Q3) [2]		6.710 (5.380, 8.031)	7.800 (5.472, 10.047)
	(95% CI)		(2.801, 10.616)	(1.289, 14.645)
	LS Means Difference (95% CI)			1.090 (-8.868, 11.315)
	p-value			0.8543
	Corrected Hedges' G (95% CI)			11.3877 (7.9558, 14.8196)
≥ 68 letters BCVA Score Change from Baseline to 11 Months [1]	n		7	12
	Mean (SD)		4.7 (7.16)	3.3 (5.10)
	Median		0.0	4.5
	Min, Max		-2, 13	-8, 9
	LS Means (Q1, Q3) [2]		4.258 (2.843, 5.709)	3.776 (3.037, 4.491)
	(95% CI)		(0.121, 8.186)	(1.702, 5.889)
	LS Means Difference (95% CI)			-0.482 (-6.323, 5.562)
	p-value			0.6425
	Corrected Hedges' G (95% CI)			-10.4535 (-14.0558, -6.8513)

Note: BCVA = Best Corrected Visual Acuity.

Note: The trimmed means adaptive approach assigns a percentile floor in the treatment arm based on the greatest proportion of dropouts observed between the two arms. Those observations with missing data at 11 months had values worse than the percentile floor imputed to calculate the adjusted floor in which the best observations were subset. Observations are ranked based on baseline adjusted 11-month scores. The p-value to test the LS Means difference was determined by taking the proportion of values in a 10,000 permutation distribution more extreme than the observed effect. The 95% CI surrounding the LS means difference was determined by taking the 2.5 and 97.5 percentiles from the same permutation distribution. The PROC MULTTEST procedure in SAS v9.4 was used to produce one dataset containing 10,000 permuted treatment effects. The procedure used seed 2830.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] Q1 = 25th percentile, Q3 = 75th percentile.

Reference Listing: 16.2.6.1

Table Morb_47

BCVA Change from Baseline - Analysis of Covariance by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	BCVA Score Change from Baseline to 11 Months [1]	n	13	11
		Mean (SD)	9.7 (10.10)	3.2 (11.14)
		Median	9.0	4.0
		Min, Max	-5, 27	-14, 20
	LS Means (SE)		9.692 (3.0026)	3.182 (3.2641)
	(95% CI)		(3.448, 15.936)	(-3.606, 9.970)
	LS Means Difference (SE)			-6.510 (4.4351)
	(95% CI)			(-15.733, 2.713)
	p-value [2]			0.1570
	Corrected Hedges' G (95% CI)			-0.5806 (-1.4014, 0.2402)
≥ 68 letters	BCVA Score Change from Baseline to 11 Months [1]	n	7	12
		Mean (SD)	4.7 (7.16)	3.3 (5.10)
		Median	0.0	4.5
		Min, Max	-2, 13	-8, 9
	LS Means (SE)		4.852 (2.3047)	3.170 (1.7544)
	(95% CI)		(-0.034, 9.738)	(-0.550, 6.889)
	LS Means Difference (SE)			-1.682 (2.9135)
	(95% CI)			(-7.859, 4.494)
	p-value [2]			0.5717
	Corrected Hedges' G (95% CI)			-0.2641 (-1.2004, 0.6722)

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

[2] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_47

DATE: 16MAY2024 8:34

Table Morb_48

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter [1]	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	BCVA Score Change from Baseline to 11 Months [2]	n	13	11
		Mean (SD)	9.7 (10.10)	3.2 (11.14)
		Median	9.0	4.0
		Min, Max	-5, 27	-14, 20
	LS Means (SE)		7.427 (3.3785)	2.285 (3.9320)
	(95% CI)		(0.798, 14.057)	(-5.429, 10.000)
	LS Means Difference (SE)			-5.142 (5.1136)
	(95% CI)			(-15.174, 4.890)
	p-value [3]			0.3148
	Corrected Hedges' G (95% CI)			-0.3947 (-1.2059, 0.4166)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_48

DATE: 15MAY2024 13:02

Table Morb_48

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Baseline BCVA Score in NORSE-1 Study (ITT Population)

Subgroup	Parameter [1]	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	BCVA Score Change from Baseline to 11 Months [2]	n	7	12
		Mean (SD)	4.7 (7.16)	3.3 (5.10)
		Median	0.0	4.5
		Min, Max	-2, 13	-8, 9
	LS Means (SE)		6.811 (3.6611)	3.697 (2.6252)
	(95% CI)		(-0.375, 13.997)	(-1.454, 8.847)
	LS Means Difference (SE)			-3.114 (4.5733)
	(95% CI)			(-12.091, 5.862)
	p-value [3]			0.4961
	Corrected Hedges' G (95% CI)			-0.3196 (-1.2578, 0.6186)

Note: BCVA = Best Corrected Visual Acuity.

Note: Missing 11-month BCVA values were replaced using the multiple imputation method with a set of plausible values that represented the uncertainty of the correct value based on the observed time matched data at all other visits. The multiple imputation was completed by two steps (1) impute these intermittent missing data using Markov chain Monte Carlo (MCMC) methods to get a monotone missingness data pattern; (2) then use regression method to impute missing data. Proc MI and Proc MIANALYZE in SAS were used to generate the datasets and run these analyses. This method of imputation assumed that missing data are missing at random (MAR).

[1] The 95% confidence intervals and the p-values are based on the overall estimates from 100 imputations, testing the ONS-5010 treatment group versus the ranibizumab treatment group using the difference between month 11 and baseline.

[2] Summary statistics based on observed changes from baseline to 11 months.

[3] p-value using analysis of covariance (ANCOVA) with treatment group as fixed effect and baseline BCVA as a continuous covariate. The p-value is testing the difference in LS Means between the treatment arms.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_48

DATE: 15MAY2024 13:02

Table Morb_49

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Day 30	BCVA Score Change from Baseline	n	20	13
			Mean (SD)	5.3 (8.40)	3.5 (8.69)
			Median	2.0	3.0
			Min, Max	-9, 24	-11, 22
		LS Means (SE) [1]		5.250 (2.1890)	3.538 (2.7152)
		(95% CI)		(0.716, 9.784)	(-2.085, 9.162)
		LS Means Difference (SE)			-1.712 (3.4877)
		(95% CI)			(-8.935, 5.512)
≤ 67 letters	Day 60		p-value		0.6284
		Corrected Hedges' G (95% CI)			-0.1706 (-0.8701, 0.5290)
		BCVA Score Change from Baseline	n	20	13
			Mean (SD)	6.1 (7.94)	4.2 (7.06)
			Median	7.0	4.0
			Min, Max	-8, 20	-9, 14
		LS Means (SE) [1]		6.050 (1.9156)	4.231 (2.3760)
		(95% CI)		(2.038, 10.062)	(-0.746, 9.207)
		LS Means Difference (SE)			-1.819 (3.0520)
		(95% CI)			(-8.211, 4.573)
		p-value			0.5582
		Corrected Hedges' G (95% CI)			-0.2072 (-0.9073, 0.4930)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_49

DATE: 16MAY2024 9:25

Table Morb_49

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Day 90	BCVA Score Change from Baseline	n	20	13
			Mean (SD)	6.6 (8.11)	4.5 (9.79)
			Median	8.0	6.0
			Min, Max	-14, 20	-24, 14
		LS Means (SE) [1]		6.600 (2.1777)	4.462 (2.7011)
		(95% CI)		(2.143, 11.057)	(-1.067, 9.990)
		LS Means Difference (SE)			-2.138 (3.4696)
		(95% CI)			(-9.240, 4.963)
≤ 67 letters	Day 120		p-value		0.5426
		Corrected Hedges' G (95% CI)			-0.2142 (-0.9145, 0.4861)
		BCVA Score Change from Baseline	n	19	12
			Mean (SD)	6.6 (10.99)	3.7 (6.77)
			Median	8.0	2.5
			Min, Max	-13, 29	-5, 14
		LS Means (SE) [1]		5.415 (2.7564)	1.093 (3.4349)
		(95% CI)		(-0.217, 11.048)	(-5.923, 8.109)
		LS Means Difference (SE)			-4.322 (4.4042)
		(95% CI)			(-13.320, 4.675)
		p-value			0.3343
		Corrected Hedges' G (95% CI)			-0.3516 (-1.0799, 0.3767)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_49

DATE: 16MAY2024 9:25

Table Morb_49

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Day 150	BCVA Score Change from Baseline	n	18	11
			Mean (SD)	6.2 (7.66)	3.6 (7.61)
			Median	4.5	3.0
			Min, Max	-5, 24	-9, 14
		LS Means (SE) [1]		5.546 (1.9552)	3.067 (2.4379)
		(95% CI)		(1.565, 9.527)	(-1.896, 8.031)
		LS Means Difference (SE)			-2.478 (3.1251)
		(95% CI)			(-8.841, 3.884)
≤ 67 letters	Day 180		p-value		0.4335
		Corrected Hedges' G (95% CI)			-0.2931 (-1.0472, 0.4610)
		BCVA Score Change from Baseline	n	18	12
			Mean (SD)	8.5 (9.27)	4.8 (8.76)
			Median	8.0	3.0
			Min, Max	-8, 27	-10, 18
		LS Means (SE) [1]		7.819 (2.2606)	3.346 (2.7892)
		(95% CI)		(3.200, 12.438)	(-2.356, 9.048)
		LS Means Difference (SE)			-4.472 (3.5902)
		(95% CI)			(-11.811, 2.866)
		p-value			0.2227
		Corrected Hedges' G (95% CI)			-0.4524 (-1.1923, 0.2875)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_49

DATE: 16MAY2024 9:25

Table Morb_49

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Day 210	BCVA Score Change from Baseline	n	17	11
			Mean (SD)	6.9 (11.91)	3.0 (8.23)
			Median	5.0	4.0
			Min, Max	-22, 33	-11, 14
		LS Means (SE) [1]		6.382 (2.4559)	1.751 (3.0366)
		(95% CI)		(1.348, 11.415)	(-4.474, 7.977)
		LS Means Difference (SE)			-4.630 (3.9055)
		(95% CI)			(-12.636, 3.376)
≤ 67 letters	Day 240		p-value		0.2459
		Corrected Hedges' G (95% CI)			-0.4449 (-1.2127, 0.3230)
		BCVA Score Change from Baseline	n	14	11
			Mean (SD)	9.8 (10.47)	3.1 (7.63)
			Median	10.0	5.0
			Min, Max	-3, 38	-10, 12
		LS Means (SE) [1]		7.240 (2.2603)	2.197 (2.7130)
		(95% CI)		(2.609, 11.871)	(-3.377, 7.770)
		LS Means Difference (SE)			-5.043 (3.5312)
		(95% CI)			(-12.289, 2.203)
			p-value		0.1647
		Corrected Hedges' G (95% CI)			-0.5608 (-1.3667, 0.2451)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_49

DATE: 16MAY2024 9:25

Table Morb_49

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Day 270	BCVA Score Change from Baseline	n	14	11
			Mean (SD)	7.9 (14.12)	3.1 (9.71)
			Median	11.0	5.0
			Min, Max	-16, 38	-13, 14
		LS Means (SE) [1]		5.080 (2.9392)	2.108 (3.4537)
		(95% CI)		(-0.934, 11.094)	(-4.983, 9.200)
		LS Means Difference (SE)			-2.971 (4.5351)
		(95% CI)			(-12.270, 6.327)
≤ 67 letters	Day 300		p-value		0.5178
		Corrected Hedges' G (95% CI)			-0.2566 (-1.0497, 0.5365)
		BCVA Score Change from Baseline	n	13	10
			Mean (SD)	9.5 (9.79)	2.0 (9.89)
			Median	10.0	3.5
			Min, Max	-4, 25	-12, 17
		LS Means (SE) [1]		6.255 (2.5057)	1.829 (2.9107)
		(95% CI)		(1.163, 11.347)	(-4.100, 7.758)
		LS Means Difference (SE)			-4.426 (3.8407)
		(95% CI)			(-12.241, 3.389)
		p-value			0.2575
		Corrected Hedges' G (95% CI)			-0.4684 (-1.3047, 0.3679)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_49

DATE: 16MAY2024 9:25

Table Morb_49

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Day 330	BCVA Score Change from Baseline	n	13	11
			Mean (SD)	9.7 (10.10)	3.2 (11.14)
			Median	9.0	4.0
			Min, Max	-5, 27	-14, 20
		LS Means (SE) [1]		6.643 (2.7460)	2.551 (3.1083)
		(95% CI)		(1.021, 12.265)	(-3.826, 8.928)
		LS Means Difference (SE)			-4.092 (4.1476)
		(95% CI)			(-12.593, 4.409)
		p-value			0.3324
		Corrected Hedges' G (95% CI)			-0.3916 (-1.2027, 0.4195)
≤ 67 letters	Day 365	BCVA Score Change from Baseline	n		11
			Mean (SD)		2.5 (10.36)
			Median		2.0
			Min, Max		-11, 20

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_49

DATE: 16MAY2024 9:25

Table Morb_49

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	Day 30	BCVA Score Change from Baseline	n	9	15
			Mean (SD)	5.3 (4.47)	1.5 (4.16)
			Median	7.0	2.0
			Min, Max	-2, 10	-5, 8
		LS Means (SE) [1]		5.333 (1.6983)	1.533 (1.3155)
		(95% CI)		(1.766, 8.900)	(-1.230, 4.296)
		LS Means Difference (SE)			-3.800 (2.1482)
		(95% CI)			(-8.312, 0.712)
≥ 68 letters	Day 60		p-value		0.0938
		Corrected Hedges' G (95% CI)			-0.7201 (-1.5730, 0.1328)
		BCVA Score Change from Baseline	n	8	14
			Mean (SD)	4.1 (7.43)	0.9 (4.62)
			Median	6.5	0.0
			Min, Max	-10, 13	-10, 10
		LS Means (SE) [1]		4.322 (2.0703)	1.295 (1.5886)
		(95% CI)		(0.129, 8.516)	(-1.924, 4.514)
		LS Means Difference (SE)			-3.028 (2.6096)
		(95% CI)			(-8.314, 2.259)
		p-value			0.2534
		Corrected Hedges' G (95% CI)			-0.4925 (-1.3743, 0.3892)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_49

DATE: 16MAY2024 9:25

Table Morb_49

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	Day 90	BCVA Score Change from Baseline	n	8	14
			Mean (SD)	6.5 (8.16)	3.4 (3.67)
			Median	8.0	4.5
			Min, Max	-4, 16	-6, 9
		LS Means (SE) [1]		6.683 (1.8920)	3.834 (1.4519)
		(95% CI)		(2.821, 10.545)	(0.868, 6.799)
		LS Means Difference (SE)			-2.849 (2.3849)
		(95% CI)			(-7.718, 2.020)
≥ 68 letters	Day 120		p-value		0.2415
		Corrected Hedges' G (95% CI)			-0.5072 (-1.3897, 0.3754)
		BCVA Score Change from Baseline	n	8	14
			Mean (SD)	7.3 (7.07)	0.9 (6.70)
			Median	10.0	2.0
			Min, Max	-1, 15	-11, 9
		LS Means (SE) [1]		7.430 (2.0333)	1.256 (1.5564)
		(95% CI)		(3.315, 11.545)	(-1.896, 4.407)
		LS Means Difference (SE)			-6.174 (2.5607)
		(95% CI)			(-11.357, -0.991)
		p-value			0.0208
		Corrected Hedges' G (95% CI)			-1.0244 (-1.9483, -0.1005)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_49

DATE: 16MAY2024 9:25

Table Morb_49

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	Day 150	BCVA Score Change from Baseline	n	8	13
			Mean (SD)	4.3 (6.54)	0.8 (7.97)
			Median	3.0	1.0
			Min, Max	-4, 14	-12, 11
		LS Means (SE) [1]		4.429 (2.1867)	1.237 (1.7001)
		(95% CI)		(0.012, 8.845)	(-2.197, 4.670)
		LS Means Difference (SE)			-3.192 (2.7698)
		(95% CI)			(-8.786, 2.403)
≥ 68 letters	Day 180		p-value		0.2559
		Corrected Hedges' G (95% CI)			-0.4982 (-1.3928, 0.3964)
		BCVA Score Change from Baseline	n	8	13
			Mean (SD)	4.5 (6.44)	0.6 (6.68)
			Median	4.5	3.0
			Min, Max	-4, 15	-9, 10
		LS Means (SE) [1]		4.678 (1.9341)	1.148 (1.5054)
		(95% CI)		(0.750, 8.606)	(-1.909, 4.204)
		LS Means Difference (SE)			-3.530 (2.4509)
		(95% CI)			(-8.507, 1.446)
		p-value			0.1587
		Corrected Hedges' G (95% CI)			-0.6226 (-1.5249, 0.2797)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_49

DATE: 16MAY2024 9:25

Table Morb_49

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	Day 210	BCVA Score Change from Baseline	n	7	13
			Mean (SD)	4.3 (6.73)	2.8 (7.06)
			Median	7.0	5.0
			Min, Max	-4, 12	-10, 12
		LS Means (SE) [1]		4.872 (2.2324)	3.313 (1.6871)
		(95% CI)		(0.350, 9.394)	(-0.105, 6.731)
		LS Means Difference (SE)			-1.559 (2.7982)
		(95% CI)			(-7.227, 4.109)
≥ 68 letters	Day 240		p-value		0.5808
		Corrected Hedges' G (95% CI)			-0.2478 (-1.1702, 0.6745)
		BCVA Score Change from Baseline	n	7	12
			Mean (SD)	4.7 (7.13)	1.6 (5.99)
			Median	9.0	1.5
			Min, Max	-5, 12	-8, 12
		LS Means (SE) [1]		5.418 (1.8966)	2.493 (1.4560)
		(95% CI)		(1.554, 9.281)	(-0.475, 5.462)
		LS Means Difference (SE)			-2.925 (2.3910)
		(95% CI)			(-7.797, 1.948)
		p-value			0.2303
		Corrected Hedges' G (95% CI)			-0.5549 (-1.5052, 0.3954)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_49

DATE: 16MAY2024 9:25

Table Morb_49

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	Day 270	BCVA Score Change from Baseline	n	6	12
			Mean (SD)	4.0 (6.57)	1.8 (6.05)
			Median	3.5	1.0
			Min, Max	-3, 13	-9, 10
		LS Means (SE) [1]		5.540 (2.4129)	2.088 (1.7770)
		(95% CI)		(0.616, 10.464)	(-1.534, 5.711)
		LS Means Difference (SE)			-3.452 (2.9966)
		(95% CI)			(-9.564, 2.660)
≥ 68 letters	Day 300		p-value		0.2582
		Corrected Hedges' G (95% CI)			-0.5407 (-1.5381, 0.4567)
		BCVA Score Change from Baseline	n	7	12
			Mean (SD)	3.1 (10.12)	3.3 (3.60)
			Median	10.0	3.0
			Min, Max	-12, 13	-3, 9
		LS Means (SE) [1]		3.872 (2.3618)	4.046 (1.8083)
		(95% CI)		(-0.932, 8.677)	(0.368, 7.724)
		LS Means Difference (SE)			0.174 (2.9746)
		(95% CI)			(-5.877, 6.224)
		p-value			0.9538
		Corrected Hedges' G (95% CI)			0.0265 (-0.9057, 0.9587)

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_49

DATE: 16MAY2024 9:25

Table Morb_49

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Visit	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	Day 330	BCVA Score Change from Baseline	n	7	12
			Mean (SD)	4.7 (7.16)	3.3 (5.10)
			Median	0.0	4.5
			Min, Max	-2, 13	-8, 9
		LS Means (SE) [1]		5.448 (2.2948)	3.976 (1.7613)
		(95% CI)		(0.780, 10.115)	(0.394, 7.559)
		LS Means Difference (SE)			-1.471 (2.8928)
≥ 68 letters	Day 365	(95% CI)			(-7.356, 4.413)
		p-value			0.6144
		Corrected Hedges' G (95% CI)			-0.2308 (-1.1661, 0.7046)
≥ 68 letters	Day 365	BCVA Score Change from Baseline	n		12
			Mean (SD)		1.4 (7.04)
			Median		2.0
			Min, Max		-12, 10

Note: Missing visit BCVA values will not be imputed. BCVA = Best Corrected Visual Acuity. The Proc Mixed procedure in SAS v9.4 was used. BCVA score was modeled using treatment, visit, and an interaction term of treatment and visit, as fixed effects. The repeated statement was used to specify a heterogeneous autoregressive covariance structure, which was determined based on modeling several covariance structures and comparing Akaike Information Criterion (AIC). The working covariance structure that produced the lowest AIC was used.

[1] LS Means, CI's, and p-values from the repeated measures model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_49

DATE: 16MAY2024 9:25

Table Morb_50

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Baseline BCVA Score in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Number of Subjects, n/N1 (%) [1]	5/ 17 (29.4)	3/ 13 (23.1)
≥ 68 letters	Number of Subjects, n/N1 (%) [1]	0/ 7	1/ 13 (7.7)
≤ 67 letters	Number of Subjects, n/N (%) [1]	5/ 21 (23.8)	3/ 15 (20.0)
≥ 68 letters	Number of Subjects, n/N (%) [1]	0/ 9	1/ 16 (6.3)

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing. 20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_50

DATE: 31MAY2024 11:18

Table Morb_51

Subjects Gaining ≥ 15 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≤ 67 letters	Number of Subjects, n/N1 (%) [1]	1/ 7 (14.3)	0/ 9
Yes and ≥ 68 letters	Number of Subjects, n/N1 (%) [1]	0/ 3	0/ 11
No and ≤ 67 letters	Number of Subjects, n/N1 (%) [1]	4/ 10 (40.0)	2/ 4 (50.0)
No and ≥ 68 letters	Number of Subjects, n/N1 (%) [1]	0/ 4	0/ 2
Yes and ≤ 67 letters	Number of Subjects, n/N (%) [1]	1/ 11 (9.1)	0/ 11
Yes and ≥ 68 letters	Number of Subjects, n/N (%) [1]	0/ 4	0/ 14
No and ≤ 67 letters	Number of Subjects, n/N (%) [1]	4/ 10 (40.0)	2/ 4 (50.0)
No and ≥ 68 letters	Number of Subjects, n/N (%) [1]	0/ 5	0/ 2

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders. Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_51

DATE: 31MAY2024 11:20

Table Morb_52

Subjects Gaining ≥ 10 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≤ 67 letters	Number of Subjects, n/N1 (%) [1]	2/ 7 (28.6)	1/ 9 (11.1)
Yes and ≥ 68 letters	Number of Subjects, n/N1 (%) [1]	0/ 3	0/ 11
No and ≤ 67 letters	Number of Subjects, n/N1 (%) [1]	4/ 10 (40.0)	2/ 4 (50.0)
No and ≥ 68 letters	Number of Subjects, n/N1 (%) [1]	3/ 4 (75.0)	0/ 2
Yes and ≤ 67 letters	Number of Subjects, n/N (%) [1]	2/ 11 (18.2)	1/ 11 (9.1)
Yes and ≥ 68 letters	Number of Subjects, n/N (%) [1]	0/ 4	0/ 14
No and ≤ 67 letters	Number of Subjects, n/N (%) [1]	4/ 10 (40.0)	2/ 4 (50.0)
No and ≥ 68 letters	Number of Subjects, n/N (%) [1]	3/ 5 (60.0)	0/ 2

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_52

DATE: 31MAY2024 11:24

Table Morb_53

Subjects Gaining ≥ 5 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≤ 67 letters	Number of Subjects, n/N1 (%) [1]	3/ 7 (42.9)	3/ 9 (33.3)
Yes and ≥ 68 letters	Number of Subjects, n/N1 (%) [1]	0/ 3	5/ 11 (45.5)
No and ≤ 67 letters	Number of Subjects, n/N1 (%) [1]	5/ 10 (50.0)	2/ 4 (50.0)
No and ≥ 68 letters	Number of Subjects, n/N1 (%) [1]	3/ 4 (75.0)	1/ 2 (50.0)
Yes and ≤ 67 letters	Number of Subjects, n/N (%) [1]	3/ 11 (27.3)	3/ 11 (27.3)
Yes and ≥ 68 letters	Number of Subjects, n/N (%) [1]	0/ 4	5/ 14 (35.7)
No and ≤ 67 letters	Number of Subjects, n/N (%) [1]	5/ 10 (50.0)	2/ 4 (50.0)
No and ≥ 68 letters	Number of Subjects, n/N (%) [1]	3/ 5 (60.0)	1/ 2 (50.0)

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_53

DATE: 31MAY2024 11:27

Table Morb_54

Subjects Loosing < 15 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≤ 67 letters	Number of Subjects, n/N1 (%) [1]	6/ 7 (85.7)	7/ 9 (77.8)
	Odds Ratio [2]		0.5833
	95% CI		(0.0085, 14.4628)
	Relative Risk [2]		0.9074
	95% CI		(0.4743, 2.0858)
	Absolute Risk Reduction [2]		-0.0794
	95% CI		(-0.4998, 0.4164)
	p-value [3]		>0.9999

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_54

DATE: 18JUN2024 13:01

Table Morb_54

Subjects Loosing < 15 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≥ 68 letters	Number of Subjects, n/N1 (%) [1]	3/ 3 (100.0)	10/ 11 (90.9)
	Odds Ratio [2]		0.0000
	95% CI		(0.0000, 69.6667)
	Relative Risk [2]		0.9091
	95% CI		(0.5869, 3.8950)
	Absolute Risk Reduction [2]		-0.0909
	95% CI		(-0.4363, 0.5942)
	p-value [3]		>0.9999

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_54

DATE: 18JUN2024 13:01

Table Morb_54

Subjects Loosing < 15 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No and ≤ 67 letters	Number of Subjects, n/N1 (%) [1]	7/ 10 (70.0)	4/ 4 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	1.4286 (0.5201, 2.8773)	
	Absolute Risk Reduction [2] 95% CI	0.3000 (-0.2986, 0.6525)	
	p-value [3]	0.5055	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_54

DATE: 18JUN2024 13:01

Table Morb_54

Subjects Loosing < 15 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No and ≥ 68 letters	Number of Subjects, n/N1 (%) [1]	4/ 4 (100.0)	2/ 2 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	NE (NE, NE)	
	Absolute Risk Reduction [2] 95% CI	NE (NE, NE)	
	p-value [3]	NE	
Interaction	p-value [4]	0.4077	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_54

DATE: 18JUN2024 13:01

Table Morb_54

Subjects Loosing < 15 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≤ 67 letters	Number of Subjects, n/N (%) [1]	6/ 11 (54.5)	7/ 11 (63.6)
	Odds Ratio [2]		1.4583
	95% CI		(0.1964, 11.1706)
	Relative Risk [2]		1.1667
	95% CI		(0.5346, 2.8997)
	Absolute Risk Reduction [2]		0.0909
	95% CI		(-0.3368, 0.4959)
	p-value [3]		>0.9999

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_54

DATE: 18JUN2024 13:01

Table Morb_54

Subjects Loosing < 15 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≥ 68 letters	Number of Subjects, n/N (%) [1]	3/ 4 (75.0)	10/ 14 (71.4)
	Odds Ratio [2]		0.8333
	95% CI		(0.0127, 14.9760)
	Relative Risk [2]		0.9524
	95% CI		(0.5106, 4.1328)
	Absolute Risk Reduction [2]		-0.0357
	95% CI		(-0.4614, 0.5331)
	p-value [3]		>0.9999

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_54

DATE: 18JUN2024 13:01

Table Morb_54

Subjects Loosing < 15 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No and ≤ 67 letters	Number of Subjects, n/N (%) [1]	7/ 10 (70.0)	4/ 4 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	1.4286 (0.5201, 2.8773)	
	Absolute Risk Reduction [2] 95% CI	0.3000 (-0.2986, 0.6525)	
	p-value [3]	0.5055	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_54

DATE: 18JUN2024 13:01

Table Morb_54

Subjects Loosing < 15 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No and ≥ 68 letters	Number of Subjects, n/N (%) [1]	4/ 5 (80.0)	2/ 2 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	1.2500 (0.1850, 3.5263)	
	Absolute Risk Reduction [2] 95% CI	0.2000 (-0.6741, 0.7164)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.9328	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_54

DATE: 18JUN2024 13:01

Table Morb_55

BCVA Change from Baseline - Trimmed Means Fixed Approach by Baseline BCVA Score and Previous Anti-VEGF Therapy in
NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≤ 67 letters	BCVA Score Change from Baseline to 11 Months [1]	n	6	7
Yes and ≥ 68 letters	BCVA Score Change from Baseline to 11 Months [1]	n	3	10
No and ≤ 67 letters	BCVA Score Change from Baseline to 11 Months [1]	n	7	4
No and ≥ 68 letters	BCVA Score Change from Baseline to 11 Months [1]	n	4	2

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_55

DATE: 30APR2024 15:01

Table Morb_56

BCVA Change from Baseline - Trimmed Means Adaptive Approach by Baseline BCVA Score and Previous Anti-VEGF Therapy
in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≤ 67 letters	BCVA Score Change from Baseline to 11 Months [1]	n	6	7
Yes and ≥ 68 letters	BCVA Score Change from Baseline to 11 Months [1]	n	3	10
No and ≤ 67 letters	BCVA Score Change from Baseline to 11 Months [1]	n	7	4
No and ≥ 68 letters	BCVA Score Change from Baseline to 11 Months [1]	n	4	2

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_56

DATE: 30APR2024 15:05

Table Morb_57

BCVA Change from Baseline - Analysis of Covariance by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≤ 67 letters	BCVA Score Change from Baseline to 11 Months [1]	n	6	7
Yes and ≥ 68 letters	BCVA Score Change from Baseline to 11 Months [1]	n	3	10
No and ≤ 67 letters	BCVA Score Change from Baseline to 11 Months [1]	n	7	4
No and ≥ 68 letters	BCVA Score Change from Baseline to 11 Months [1]	n	4	2

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_57

DATE: 30APR2024 15:09

Table Morb_58

BCVA Change from Baseline - Analysis of Covariance Multiple Imputation by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and $\leq$ 67 letters	BCVA Score Change from Baseline to 11 Months [1]	n	6	7
Yes and $\geq$ 68 letters	BCVA Score Change from Baseline to 11 Months [1]	n	3	10
No and $\leq$ 67 letters	BCVA Score Change from Baseline to 11 Months [1]	n	7	4
No and $\geq$ 68 letters	BCVA Score Change from Baseline to 11 Months [1]	n	4	2

Note: BCVA = Best Corrected Visual Acuity.

[1] Summary statistics based on observed changes from baseline to 11 months.

Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_58

DATE: 30APR2024 15:14

Table Morb_59

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score and Previous Anti-VEGF Therapy in
NORSE-1 Study
(ITT Population)

Visit	Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Day 30	Yes and ≤ 67 letters	BCVA Score Change from Baseline	n	10	9
	Yes and ≥ 68 letters	BCVA Score Change from Baseline	n	4	13
	No and ≤ 67 letters	BCVA Score Change from Baseline	n	10	4
	No and ≥ 68 letters	BCVA Score Change from Baseline	n	5	2
Day 60	Yes and ≤ 67 letters	BCVA Score Change from Baseline	n	10	9
	Yes and ≥ 68 letters	BCVA Score Change from Baseline	n	3	12
	No and ≤ 67 letters	BCVA Score Change from Baseline	n	10	4
	No and ≥ 68 letters	BCVA Score Change from Baseline	n	5	2
Day 90	Yes and ≤ 67 letters	BCVA Score Change from Baseline	n	10	9
	Yes and ≥ 68 letters	BCVA Score Change from Baseline	n	3	12
	No and ≤ 67 letters	BCVA Score Change from Baseline	n	10	4
	No and ≥ 68 letters	BCVA Score Change from Baseline	n	5	2

Note: BCVA = Best Corrected Visual Acuity.
Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients
Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_59

DATE: 30APR2024 15:18

Table Morb_59

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score and Previous Anti-VEGF Therapy in
NORSE-1 Study
(ITT Population)

Visit	Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Day 120	Yes and ≤ 67 letters	BCVA Score Change from Baseline	n	9	8
	Yes and ≥ 68 letters	BCVA Score Change from Baseline	n	3	12
	No and ≤ 67 letters	BCVA Score Change from Baseline	n	10	4
	No and ≥ 68 letters	BCVA Score Change from Baseline	n	5	2
Day 150	Yes and ≤ 67 letters	BCVA Score Change from Baseline	n	8	7
	Yes and ≥ 68 letters	BCVA Score Change from Baseline	n	3	11
	No and ≤ 67 letters	BCVA Score Change from Baseline	n	10	4
	No and ≥ 68 letters	BCVA Score Change from Baseline	n	5	2
Day 180	Yes and ≤ 67 letters	BCVA Score Change from Baseline	n	8	8
	Yes and ≥ 68 letters	BCVA Score Change from Baseline	n	3	11
	No and ≤ 67 letters	BCVA Score Change from Baseline	n	10	4
	No and ≥ 68 letters	BCVA Score Change from Baseline	n	5	2

Note: BCVA = Best Corrected Visual Acuity.
Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients
Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_59

DATE: 30APR2024 15:18

Table Morb_59

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score and Previous Anti-VEGF Therapy in
NORSE-1 Study
(ITT Population)

Visit	Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Day 210	Yes and $\leq$ 67 letters	BCVA Score Change from Baseline	n	7	7
	Yes and $\geq$ 68 letters	BCVA Score Change from Baseline	n	3	11
	No and $\leq$ 67 letters	BCVA Score Change from Baseline	n	10	4
	No and $\geq$ 68 letters	BCVA Score Change from Baseline	n	4	2
Day 240	Yes and $\leq$ 67 letters	BCVA Score Change from Baseline	n	6	7
	Yes and $\geq$ 68 letters	BCVA Score Change from Baseline	n	3	10
	No and $\leq$ 67 letters	BCVA Score Change from Baseline	n	8	4
	No and $\geq$ 68 letters	BCVA Score Change from Baseline	n	4	2
Day 270	Yes and $\leq$ 67 letters	BCVA Score Change from Baseline	n	6	7
	Yes and $\geq$ 68 letters	BCVA Score Change from Baseline	n	3	11
	No and $\leq$ 67 letters	BCVA Score Change from Baseline	n	8	4
	No and $\geq$ 68 letters	BCVA Score Change from Baseline	n	3	1

Note: BCVA = Best Corrected Visual Acuity.
Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients
Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_59

DATE: 30APR2024 15:18

Table Morb_59

BCVA Change from Baseline over Time - Repeated Measures by Baseline BCVA Score and Previous Anti-VEGF Therapy in
NORSE-1 Study
(ITT Population)

Visit	Subgroup	Parameter	Statistic	Ranibizumab (N=30)	ONS-5010 (N=31)
Day 300	Yes and ≤ 67 letters	BCVA Score Change from Baseline	n	6	6
	Yes and ≥ 68 letters	BCVA Score Change from Baseline	n	3	10
	No and ≤ 67 letters	BCVA Score Change from Baseline	n	7	4
	No and ≥ 68 letters	BCVA Score Change from Baseline	n	4	2
Day 330	Yes and ≤ 67 letters	BCVA Score Change from Baseline	n	6	7
	Yes and ≥ 68 letters	BCVA Score Change from Baseline	n	3	10
	No and ≤ 67 letters	BCVA Score Change from Baseline	n	7	4
	No and ≥ 68 letters	BCVA Score Change from Baseline	n	4	2
Day 365	Yes and ≤ 67 letters	BCVA Score Change from Baseline	n		7
	Yes and ≥ 68 letters	BCVA Score Change from Baseline	n		10
	No and ≤ 67 letters	BCVA Score Change from Baseline	n		4
	No and ≥ 68 letters	BCVA Score Change from Baseline	n		2

Note: BCVA = Best Corrected Visual Acuity.
Subgroup analysis will only be performed, if each subgroup (independent of treatment arms) contains at least 10 patients
Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_59

DATE: 30APR2024 15:18

Table Morb_60

Proportion of subjects with a visual acuity Snellen equivalent of 20/200 or worse at 11 months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≤ 67 letters	Number of Subjects, n/N1 (%) [1]	2/ 7 (28.6)	3/ 9 (33.3)
Yes and ≥ 68 letters	Number of Subjects, n/N1 (%) [1]	0/ 3	1/ 11 (9.1)
No and ≤ 67 letters	Number of Subjects, n/N1 (%) [1]	3/ 10 (30.0)	0/ 4
No and ≥ 68 letters	Number of Subjects, n/N1 (%) [1]	0/ 4	0/ 2
Yes and ≤ 67 letters	Number of Subjects, n/N (%) [1]	2/ 11 (18.2)	3/ 11 (27.3)
Yes and ≥ 68 letters	Number of Subjects, n/N (%) [1]	0/ 4	1/ 14 (7.1)
No and ≤ 67 letters	Number of Subjects, n/N (%) [1]	3/ 10 (30.0)	0/ 4
No and ≥ 68 letters	Number of Subjects, n/N (%) [1]	0/ 5	0/ 2

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing. 20/200 is the Visual-Acuity Snellen Equivalent of 35 letters.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_60

DATE: 31MAY2024 11:29

Table Morb_104

Subjects Loosing <=10 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Number of Subjects, n/N1 (%) [1]	10/ 12 (83.3)	11/ 14 (78.6)
	Odds Ratio [2]	0.7333	
	95% CI	(0.0518, 7.9569)	
	Relative Risk [2]	0.9429	
	95% CI	(0.5901, 1.5311)	
	Absolute Risk Reduction [2]	-0.0476	
	95% CI	(-0.3715, 0.2980)	
	p-value [3]	>0.9999	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_104

DATE: 12JUN2024 6:22

Table Morb_104

Subjects Loosing <=10 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	Number of Subjects, n/N1 (%) [1]	10/ 12 (83.3)	11/ 12 (91.7)
	Odds Ratio [2]	2.2000	
	95% CI	(0.0967, 141.3949)	
	Relative Risk [2]	1.1000	
	95% CI	(0.7304, 1.7319)	
	Absolute Risk Reduction [2]	0.0833	
	95% CI	(-0.2498, 0.4176)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.5194	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_104

DATE: 12JUN2024 6:22

Table Morb_104

Subjects Loosing <=10 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
< 80 years	Number of Subjects, n/N (%) [1]	10/ 17 (58.8)	11/ 17 (64.7)
	Odds Ratio [2]	1.2833	
	95% CI	(0.2603, 6.4159)	
	Relative Risk [2]	1.1000	
	95% CI	(0.6010, 2.0434)	
	Absolute Risk Reduction [2]	0.0588	
	95% CI	(-0.2756, 0.3846)	
	p-value [3]	>0.9999	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_104

DATE: 12JUN2024 6:22

Table Morb_104

Subjects Loosing <=10 Letters from Baseline to 11 Months by Age Group in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 80 years	Number of Subjects, n/N (%) [1]	10/ 13 (76.9)	11/ 14 (78.6)
	Odds Ratio [2]	1.1000	
	95% CI	(0.1179, 10.2092)	
	Relative Risk [2]	1.0214	
	95% CI	(0.6303, 1.6959)	
	Absolute Risk Reduction [2]	0.0165	
	95% CI	(-0.3167, 0.3628)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.8490	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_104

DATE: 12JUN2024 6:22

Table Morb_105

Subjects Loosing <=10 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Number of Subjects, n/N1 (%) [1]	9/ 12 (75.0)	8/ 8 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	1.3333 (0.8544, 2.3357)	
	Absolute Risk Reduction [2] 95% CI	0.2500 (-0.1368, 0.5748)	
	p-value [3]	0.2421	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_105

DATE: 18JUN2024 11:32

Table Morb_105

Subjects Loosing <=10 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	Number of Subjects, n/N1 (%) [1]	11/ 12 (91.7)	14/ 18 (77.8)
	Odds Ratio [2]	0.3182	
	95% CI	(0.0059, 3.9883)	
	Relative Risk [2]	0.8485	
	95% CI	(0.5748, 1.2853)	
	Absolute Risk Reduction [2]	-0.1389	
	95% CI	(-0.4194, 0.1837)	
	p-value [3]	0.6221	
Interaction	p-value [4]	0.1149	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_105

DATE: 18JUN2024 11:32

Table Morb_105

Subjects Loosing <=10 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Male	Number of Subjects, n/N (%) [1]	9/ 15 (60.0)	8/ 9 (88.9)
	Odds Ratio [2]	5.3333	
	95% CI	(0.4466, 275.3884)	
	Relative Risk [2]	1.4815	
	95% CI	(0.8127, 2.8259)	
	Absolute Risk Reduction [2]	0.2889	
	95% CI	(-0.1280, 0.6001)	
	p-value [3]	0.1907	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_105

DATE: 18JUN2024 11:32

Table Morb_105

Subjects Loosing <=10 Letters from Baseline to 11 Months by Gender in NORSE-1 Study
 (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Female	Number of Subjects, n/N (%) [1]	11/ 15 (73.3)	14/ 22 (63.6)
	Odds Ratio [2]	0.6364	
	95% CI	(0.1112, 3.2311)	
	Relative Risk [2]	0.8678	
	95% CI	(0.5338, 1.5098)	
	Absolute Risk Reduction [2]	-0.0970	
	95% CI	(-0.3904, 0.2248)	
	p-value [3]	0.7235	
Interaction	p-value [4]	0.1666	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_105

DATE: 18JUN2024 11:32

Table Morb_106

Subjects Loosing <=10 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Number of Subjects, n/N1 (%) [1]	9/ 10 (90.0)	16/ 20 (80.0)
	Odds Ratio [2]	0.4444	
	95% CI	(0.0081,5.6109)	
	Relative Risk [2]	0.8889	
	95% CI	(0.6176,1.4990)	
	Absolute Risk Reduction [2]	-0.1000	
	95% CI	(-0.3644,0.2572)	
	p-value [3]	0.6400	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_106

DATE: 18JUN2024 11:39

Table Morb_106

Subjects Loosing <=10 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No	Number of Subjects, n/N1 (%) [1]	11/ 14 (78.6)	6/ 6 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	1.2727 (0.6620, 2.0324)	
	Absolute Risk Reduction [2] 95% CI	0.2143 (-0.2523, 0.5094)	
	p-value [3]	0.5211	
Interaction	p-value [4]	0.2238	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_106

DATE: 18JUN2024 11:39

Table Morb_106

Subjects Loosing <=10 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes	Number of Subjects, n/N (%) [1]	9/ 15 (60.0)	16/ 25 (64.0)
	Odds Ratio [2] 95% CI	1.1852 (0.2552, 5.2973)	
	Relative Risk [2] 95% CI	1.0667 (0.6392, 1.9901)	
	Absolute Risk Reduction [2] 95% CI	0.0400 (-0.2686, 0.3570)	
	p-value [3]	>0.9999	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_106

DATE: 18JUN2024 11:39

Table Morb_106

Subjects Loosing <=10 Letters from Baseline to 11 Months by Prior Anti-VEGF Therapy in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No	Number of Subjects, n/N (%) [1]	11/ 15 (73.3)	6/ 6 (100.0)
	Odds Ratio [2] 95% CI	NE (NE,NE)	
	Relative Risk [2] 95% CI	1.3636 (0.7055,2.2272)	
	Absolute Risk Reduction [2] 95% CI	0.2667 (-0.2136,0.5548)	
	p-value [3]	0.2807	
Interaction	p-value [4]	0.7531	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_106

DATE: 18JUN2024 11:39

Table Morb_107

Subjects Loosing <=10 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Number of Subjects, n/N1 (%) [1]	13/ 17 (76.5)	10/ 13 (76.9)
	Odds Ratio [2]	1.0256	
	95% CI	(0.1367, 8.6540)	
	Relative Risk [2]	1.0059	
	95% CI	(0.5762, 1.5759)	
	Absolute Risk Reduction [2]	0.0045	
	95% CI	(-0.3360, 0.3236)	
	p-value [3]	>0.9999	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_107

DATE: 12JUN2024 6:30

Table Morb_107

Subjects Loosing <=10 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	Number of Subjects, n/N1 (%) [1]	7/ 7 (100.0)	12/ 13 (92.3)
	Odds Ratio [2]	0.0000	
	95% CI	(0.0000, 35.2857)	
	Relative Risk [2]	0.9231	
	95% CI	(0.6397, 1.5572)	
	Absolute Risk Reduction [2]	-0.0769	
	95% CI	(-0.3670, 0.3210)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.8749	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_107

DATE: 12JUN2024 6:30

Table Morb_107

Subjects Loosing <=10 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≤ 67 letters	Number of Subjects, n/N (%) [1]	13/ 21 (61.9)	10/ 15 (66.7)
	Odds Ratio [2]	1.2308	
	95% CI	(0.2531, 6.3495)	
	Relative Risk [2]	1.0769	
	95% CI	(0.5612, 1.8484)	
	Absolute Risk Reduction [2]	0.0476	
	95% CI	(-0.2837, 0.3584)	
	p-value [3]	>0.9999	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_107

DATE: 12JUN2024 6:30

Table Morb_107

Subjects Loosing <=10 Letters from Baseline to 11 Months by Baseline BCVA Score in NORSE-1 Study
(ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
≥ 68 letters	Number of Subjects, n/N (%) [1]	7/ 9 (77.8)	12/ 16 (75.0)
	Odds Ratio [2] 95% CI	0.8571 (0.0626, 8.0360)	
	Relative Risk [2] 95% CI	0.9643 (0.5895, 1.8604)	
	Absolute Risk Reduction [2] 95% CI	-0.0278 (-0.3676, 0.3793)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.7880	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_107

DATE: 12JUN2024 6:30

Table Morb_108

Subjects Loosing <=10 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≤ 67 letters	Number of Subjects, n/N1 (%) [1]	6/ 7 (85.7)	6/ 9 (66.7)
	Odds Ratio [2]		0.3333
	95% CI		(0.0055, 6.0371)
	Relative Risk [2]		0.7778
	95% CI		(0.3415, 1.6884)
	Absolute Risk Reduction [2]		-0.1905
	95% CI		(-0.6170, 0.3065)
	p-value [3]		0.5846

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_108

DATE: 18JUN2024 13:08

Table Morb_108

Subjects Loosing <=10 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≥ 68 letters	Number of Subjects, n/N1 (%) [1]	3/ 3 (100.0)	10/ 11 (90.9)
	Odds Ratio [2]		0.0000
	95% CI		(0.0000, 69.6667)
	Relative Risk [2]		0.9091
	95% CI		(0.5869, 3.8950)
	Absolute Risk Reduction [2]		-0.0909
	95% CI		(-0.4363, 0.5942)
	p-value [3]		>0.9999

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_108

DATE: 18JUN2024 13:08

Table Morb_108

Subjects Loosing <=10 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No and ≤ 67 letters	Number of Subjects, n/N1 (%) [1]	7/ 10 (70.0)	4/ 4 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	1.4286 (0.5201, 2.8773)	
	Absolute Risk Reduction [2] 95% CI	0.3000 (-0.2986, 0.6525)	
	p-value [3]	0.5055	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_108

DATE: 18JUN2024 13:08

Table Morb_108

Subjects Loosing <=10 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No and ≥ 68 letters	Number of Subjects, n/N1 (%) [1]	4/ 4 (100.0)	2/ 2 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	NE (NE, NE)	
	Absolute Risk Reduction [2] 95% CI	NE (NE, NE)	
	p-value [3]	NE	
Interaction	p-value [4]	0.3414	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

Table Morb_108

Subjects Loosing <=10 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≤ 67 letters	Number of Subjects, n/N (%) [1]	6/ 11 (54.5)	6/ 11 (54.5)
	Odds Ratio [2]		1.0000
	95% CI		(0.1386, 7.2129)
	Relative Risk [2]		1.0000
	95% CI		(0.3789, 2.6389)
	Absolute Risk Reduction [2]		0.0000
	95% CI		(-0.4356, 0.4356)
	p-value [3]		>0.9999

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_108

DATE: 18JUN2024 13:08

Table Morb_108

Subjects Loosing <=10 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
Yes and ≥ 68 letters	Number of Subjects, n/N (%) [1]	3/ 4 (75.0)	10/ 14 (71.4)
	Odds Ratio [2]		0.8333
	95% CI		(0.0127, 14.9760)
	Relative Risk [2]		0.9524
	95% CI		(0.5106, 4.1328)
	Absolute Risk Reduction [2]		-0.0357
	95% CI		(-0.4614, 0.5331)
	p-value [3]		>0.9999

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_108

DATE: 18JUN2024 13:08

Table Morb_108

Subjects Loosing <=10 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No and ≤ 67 letters	Number of Subjects, n/N (%) [1]	7/ 10 (70.0)	4/ 4 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	1.4286 (0.5201, 2.8773)	
	Absolute Risk Reduction [2] 95% CI	0.3000 (-0.2986, 0.6525)	
	p-value [3]	0.5055	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_108

DATE: 18JUN2024 13:08

Table Morb_108

Subjects Loosing <=10 Letters from Baseline to 11 Months by Baseline BCVA Score and Previous Anti-VEGF Therapy in NORSE-1 Study (ITT Population)

Subgroup	Parameter	Ranibizumab (N=30)	ONS-5010 (N=31)
No and ≥ 68 letters	Number of Subjects, n/N (%) [1]	4/ 5 (80.0)	2/ 2 (100.0)
	Odds Ratio [2] 95% CI	NE (NE, NE)	
	Relative Risk [2] 95% CI	1.2500 (0.1850, 3.5263)	
	Absolute Risk Reduction [2] 95% CI	0.2000 (-0.6741, 0.7164)	
	p-value [3]	>0.9999	
Interaction	p-value [4]	0.9592	

Note: Those subjects who received rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as non-responders (or treatment failures). Those subjects who have missing 11-month values and did not receive rescue/prohibited therapy or discontinued treatment due to adverse event or lack-of-efficacy are treated as missing.

N = number of subjects in ITT population.

[1] n = number of subjects meeting criteria, N1 = number of subjects with Month 11 assessment.

[2] Odds Ratio, Relative Risk and Absolute Risk Reduction estimate with the corresponding 95% CIs were calculated using PROC FREQ.

[3] p-value was calculated using PROC FREQ by Fisher's exact test method.

[4] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

NE = Not estimable

Reference Listing: 16.2.6.1

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Morb_108

DATE: 18JUN2024 13:08

Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE	n (%)	13 (76.5)	14 (82.4)	1.4359 (0.2685, 7.6777)	1.0769 (0.7639, 1.5182)	0.0588 (-0.2123, 0.3299) 0.6761
Eye disorders	n (%)	6 (35.3)	10 (58.8)	2.6190 (0.6546, 10.4784)	1.6667 (0.7821, 3.5517)	0.2353 (-0.0908, 0.5614) 0.1757
Conjunctival haemorrhage	n (%)	0	3 (17.6)	-	-	-
Visual acuity reduced	n (%)	2 (11.8)	1 (5.9)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

DATE: 16JUL2024 5:34

Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Eye pain	n (%)	0	2 (11.8)	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	2 (11.8)	0	-	-	-	-
				-	-	-	-
Blepharitis	n (%)	0	1 (5.9)	-	-	-	-
				-	-	-	-
Blindness transient	n (%)	0	1 (5.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

DATE: 16JUL2024 5:34

Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Keratopathy	n (%)	0	1 (5.9)	-	-	-	-
				-	-	-	-
Lenticular opacities	n (%)	0	1 (5.9)	-	-	-	-
				-	-	-	-
Seasonal allergy	n (%)	0	1 (5.9)	-	-	-	-
				-	-	-	-
Subretinal fluid	n (%)	0	1 (5.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

DATE: 16JUL2024 5:34

Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Vitreous detachment	n (%)	0	1 (5.9)	-	-	-	-
				-	-	-	-
Abnormal sensation in eye	n (%)	1 (5.9)	0	-	-	-	-
				-	-	-	-
Cataract	n (%)	1 (5.9)	0	-	-	-	-
				-	-	-	-
Neovascular age-related macular degeneration	n (%)	1 (5.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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DATE: 16JUL2024 5:34

Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years							
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	
MedDRA Preferred Term	Statistic	Ranibizumab (N=17)	(Masked Data)[1] (N=17)			p-value[2]	
Investigations	n (%)	5 (29.4)	5 (29.4)	1.0000 (0.2287, 4.3728)	1.0000 (0.3529, 2.8334)	0.0000 (-0.3063, 0.3063) >0.9999	
White blood cells urine positive	n (%)	3 (17.6)	2 (11.8)	- -	- -	- -	
Blood triglycerides increased	n (%)	1 (5.9)	1 (5.9)	- -	- -	- -	
Intraocular pressure increased	n (%)	1 (5.9)	1 (5.9)	- -	- -	- -	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood urea increased	n (%)	2 (11.8)	0	-	-	-	-
Eosinophil count increased	n (%)	0	1 (5.9)	-	-	-	-
Platelet morphology abnormal	n (%)	0	1 (5.9)	-	-	-	-
Blood creatinine increased	n (%)	1 (5.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) [1]	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value [2]
Investigations							
Blood sodium increased	n (%)	1 (5.9)	0	-	-	-	-
				-	-	-	-
Protein urine present	n (%)	1 (5.9)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	2 (11.8)	2 (11.8)	-	-	-	-
				-	-	-	-
Urinary tract infection	n (%)	0	2 (11.8)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Infections and infestations						
Tooth infection	n (%)	0	1 (5.9)	-	-	-
				-	-	-
Conjunctivitis	n (%)	1 (5.9)	0	-	-	-
				-	-	-
Influenza	n (%)	1 (5.9)	0	-	-	-
				-	-	-
Blood and lymphatic system disorders	n (%)	0	2 (11.8)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Blood and lymphatic system disorders							
Lymphadenopathy	n (%)	0	1 (5.9)	-	-	-	-
				-	-	-	-
Macrocytosis	n (%)	0	1 (5.9)	-	-	-	-
				-	-	-	-
Gastrointestinal disorders	n (%)	1 (5.9)	1 (5.9)	-	-	-	-
				-	-	-	-
Pancreatitis	n (%)	0	1 (5.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders						
Tooth abscess	n (%)	1 (5.9)	0	-	-	-
				-	-	-
Musculoskeletal and connective tissue disorders	n (%)	2 (11.8)	0	-	-	-
				-	-	-
Ankle fracture	n (%)	1 (5.9)	0	-	-	-
				-	-	-
Back pain	n (%)	1 (5.9)	0	-	-	-
				-	-	-

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) [1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Endocrine disorders	n (%)	0	1 (5.9)	-	-	-
Hyperthyroidism	n (%)	0	1 (5.9)	-	-	-
Metabolism and nutrition disorders	n (%)	0	1 (5.9)	-	-	-
Hypercholesterolaemia	n (%)	0	1 (5.9)	-	-	-

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Metabolism and nutrition disorders							
Type 2 diabetes mellitus	n (%)	0	1 (5.9)	-	-	-	-
Renal and urinary disorders	n (%)	0	1 (5.9)	-	-	-	-
Glycosuria	n (%)	0	1 (5.9)	-	-	-	-
General disorders and administration site conditions	n (%)	1 (5.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain		n (%)	1 (5.9)	0	-	-	-
					-	-	-
Injury, poisoning and procedural complications							
Contusion		n (%)	1 (5.9)	0	-	-	-
					-	-	-
Psychiatric disorders							
		n (%)	1 (5.9)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Psychiatric disorders							
Insomnia	n (%)	1 (5.9)	0	-	-	-	-
				-	-	-	-
Vascular disorders	n (%)	1 (5.9)	0	-	-	-	-
				-	-	-	-
Hypertension	n (%)	1 (5.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	
MedDRA Preferred Term	Statistic	Ranibizumab (N=13)	(Masked Data)[1] (N=14)			p-value[2]	
At Least 1 TEAE	n (%)	7 (53.8)	11 (78.6)	3.1429 (0.5864, 16.8448)	1.4592 (0.8229, 2.5875)	0.2473 (-0.0986, 0.5931) 0.1814	
Eye disorders	n (%)	6 (46.2)	6 (42.9)	0.8750 (0.1914, 3.9994)	0.9286 (0.3997, 2.1573)	-0.0330 (-0.4080, 0.3420) 0.8658	
Conjunctival haemorrhage	n (%)	2 (15.4)	2 (14.3)	- -	- -	- - -	
Posterior capsule opacification	n (%)	0	2 (14.3)	- -	- -	- - -	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) [1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value [2]
Eye disorders							
Visual acuity reduced		n (%)	2 (15.4)	0	-	-	-
					-	-	-
Choroidal neovascularisation		n (%)	0	1 (7.1)	-	-	-
					-	-	-
Conjunctivitis allergic		n (%)	0	1 (7.1)	-	-	-
					-	-	-
Corneal scar		n (%)	0	1 (7.1)	-	-	-
					-	-	-

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Dry eye	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Punctate keratitis	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Visual impairment	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Blepharitis	n (%)	1 (7.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) [1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value [2]
Eye disorders							
Diabetic retinal oedema		n (%)	1 (7.7)	0	-	-	-
					-	-	-
Neovascular age-related macular degeneration		n (%)	1 (7.7)	0	-	-	-
					-	-	-
Scleromalacia		n (%)	1 (7.7)	0	-	-	-
					-	-	-
Investigations		n (%)	3 (23.1)	4 (28.6)	1.3333 (0.2353, 7.5562)	1.2381 (0.3399, 4.5097)	0.0549 (-0.2744, 0.3843) 0.7494

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
White blood cells urine positive	n (%)	1 (7.7)	2 (14.3)	- -	- -		- -
Blood creatinine increased	n (%)	0	2 (14.3)	- -	- -		- -
Blood urea increased	n (%)	1 (7.7)	1 (7.1)	- -	- -		- -
Blood albumin increased	n (%)	0	1 (7.1)	- -	- -		- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

DATE: 16JUL2024 5:34

Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) [1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure systolic increased		n (%)	0	1 (7.1)	-	-	-
Protein urine present		n (%)	0	1 (7.1)	-	-	-
Red blood cell rouleaux formation present		n (%)	0	1 (7.1)	-	-	-
Red blood cells urine positive		n (%)	0	1 (7.1)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

DATE: 16JUL2024 5:34

Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Urinary casts	n (%)	0	1 (7.1)	-	-		-
				-	-		-
Aspartate aminotransferase increased	n (%)	1 (7.7)	0	-	-		-
				-	-		-
Blood glucose increased	n (%)	1 (7.7)	0	-	-		-
				-	-		-
Blood lactate dehydrogenase increased	n (%)	1 (7.7)	0	-	-		-
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

DATE: 16JUL2024 5:34

Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Eosinophil count increased	n (%)	1 (7.7)	0	-	-	-	-
Platelet count decreased	n (%)	1 (7.7)	0	-	-	-	-
Infections and infestations	n (%)	1 (7.7)	4 (28.6)	-	-	-	-
Influenza	n (%)	1 (7.7)	1 (7.1)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

DATE: 16JUL2024 5:34

Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Infections and infestations							
Lower respiratory tract infection	n (%)	1 (7.7)	1 (7.1)	-	-	-	-
Candida infection	n (%)	0	1 (7.1)	-	-	-	-
Endophthalmitis	n (%)	0	1 (7.1)	-	-	-	-
Kidney infection	n (%)	0	1 (7.1)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Infections and infestations							
Urinary tract infection	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Musculoskeletal and connective tissue disorders	n (%)	2 (15.4)	2 (14.3)	-	-	-	-
				-	-	-	-
Back pain	n (%)	1 (7.7)	1 (7.1)	-	-	-	-
				-	-	-	-
Rheumatoid arthritis	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) [1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Musculoskeletal and connective tissue disorders						
Wrist fracture	n (%)	1 (7.7)	0	-	-	-
				-	-	-
Gastrointestinal disorders	n (%)	1 (7.7)	1 (7.1)	-	-	-
				-	-	-
Diarrhoea	n (%)	0	1 (7.1)	-	-	-
				-	-	-
Vomiting	n (%)	1 (7.7)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic	Ranibizumab (N=13)	(Masked Data)[1] (N=14)			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	1 (7.7)	1 (7.1)	-	-	-
Basal cell carcinoma	n (%)	1 (7.7)	1 (7.1)	-	-	-
Skin and subcutaneous tissue disorders	n (%)	2 (15.4)	0	-	-	-
Brow ptosis	n (%)	1 (7.7)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Skin laceration	n (%)	1 (7.7)	0	-	-	-	-
				-	-	-	-
Immune system disorders	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Seasonal allergy	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Injury, poisoning and procedural complications	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications							
Macular scar	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Psychiatric disorders	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Confusional state	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Renal and urinary disorders	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders							
Renal tubular acidosis	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Vascular disorders	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Dizziness	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
General disorders and administration site conditions	n (%)	1 (7.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

DATE: 16JUL2024 5:34

Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain		n (%)	1 (7.7)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

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Table Saf_12

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 TEAE	p-value [3]	0.5113
Eye disorders	p-value [3]	0.2536
Investigations	p-value [3]	0.8368

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_12

DATE: 16JUL2024 5:34

Table Saf_13

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE	n (%)	2 (11.8)	1 (5.9)	-	-	-
				-	-	-
Musculoskeletal and connective tissue disorders	n (%)	2 (11.8)	0	-	-	-
Ankle fracture	n (%)	1 (5.9)	0	-	-	-
				-	-	-
Back pain	n (%)	1 (5.9)	0	-	-	-
				-	-	-
Eye disorders	n (%)	0	1 (5.9)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_13

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Table Saf_13

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) [1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Eye disorders						
Blindness transient	n (%)	0	1 (5.9)	-	-	-
				-	-	-
Investigations	n (%)	0	1 (5.9)	-	-	-
				-	-	-
Intraocular pressure increased	n (%)	0	1 (5.9)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_13

DATE: 10JUL2024 8:26

Table Saf_13

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) [1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE	n (%)	0	3 (21.4)	-	-	-
				-	-	-
Infections and infestations	n (%)	0	2 (14.3)	-	-	-
				-	-	-
Endophthalmitis	n (%)	0	1 (7.1)	-	-	-
				-	-	-
Lower respiratory tract infection	n (%)	0	1 (7.1)	-	-	-
				-	-	-
Eye disorders	n (%)	0	1 (7.1)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_13

DATE: 10JUL2024 8:26

Table Saf_13

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
 (Safety Population)

>= 80 years

MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Eye disorders						
Visual impairment	n (%)	0	1 (7.1)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_13

DATE: 10JUL2024 8:26

Table Saf_14

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Related to Study Medication Administration Procedure	n (%)	3 (17.6)	6 (35.3)	-	-	-	-
Eye disorders	n (%)	2 (11.8)	6 (35.3)	-	-	-	-
Conjunctival haemorrhage	n (%)	0	3 (17.6)	-	-	-	-
Eye pain	n (%)	0	2 (11.8)	-	-	-	-
Blindness transient	n (%)	0	1 (5.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_14

DATE: 10JUL2024 12:12

Table Saf_14

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Eye disorders						
Keratopathy	n (%)	0	1 (5.9)	-	-	-
				-	-	-
Abnormal sensation in eye	n (%)	1 (5.9)	0	-	-	-
				-	-	-
Lacrimation increased	n (%)	1 (5.9)	0	-	-	-
				-	-	-
Investigations	n (%)	1 (5.9)	1 (5.9)	-	-	-
				-	-	-
Intraocular pressure increased	n (%)	1 (5.9)	1 (5.9)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_14

DATE: 10JUL2024 12:12

Table Saf_14

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
General disorders and administration site conditions	n (%)	1 (5.9)	0	-	-	-	-
Injection site pain	n (%)	1 (5.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_14

DATE: 10JUL2024 12:12

Table Saf_14

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) [1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Related to Study Medication Administration Procedure	n (%)	3 (23.1)	3 (21.4)	-	-	-	-
Eye disorders	n (%)	2 (15.4)	2 (14.3)	-	-	-	-
Conjunctival haemorrhage	n (%)	2 (15.4)	1 (7.1)	-	-	-	-
Corneal scar	n (%)	0	1 (7.1)	-	-	-	-
Punctate keratitis	n (%)	0	1 (7.1)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_14

DATE: 10JUL2024 12:12

Table Saf_14

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

>= 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations	n (%)	0	1 (7.1)	-	-	-
Endophthalmitis	n (%)	0	1 (7.1)	-	-	-
General disorders and administration site conditions	n (%)	1 (7.7)	0	-	-	-
Injection site pain	n (%)	1 (7.7)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_14

DATE: 10JUL2024 12:12

Table Saf_15

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

< 80 years						
MedDRA System Organ Class		Ranibizumab (N=17)	ONS-5010 (Masked Data) [1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic					
At Least 1 TEAE Related to Study Drug	n (%)	4 (23.5)	2 (11.8)	-	-	-
				-	-	-
Eye disorders	n (%)	3 (17.6)	2 (11.8)	-	-	-
				-	-	-
Blindness transient	n (%)	0	1 (5.9)	-	-	-
				-	-	-
Eye pain	n (%)	0	1 (5.9)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_15

DATE: 11JUL2024 12:34

Table Saf_15

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) [1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders						
Abnormal sensation in eye	n (%)	1 (5.9)	0	-	-	-
Cataract	n (%)	1 (5.9)	0	-	-	-
Lacrimation increased	n (%)	1 (5.9)	0	-	-	-
Investigations	n (%)	1 (5.9)	1 (5.9)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_15

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

< 80 years						
MedDRA System Organ Class		Ranibizumab	ONS-5010	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Statistic	(N=17)	(Masked Data)[1] (N=17)	95% CI	95% CI	Difference 95% CI p-value
Investigations						
Intraocular pressure increased	n (%)	1 (5.9)	1 (5.9)	-	-	-
				-	-	-
General disorders and administration site conditions	n (%)	1 (5.9)	0	-	-	-
				-	-	-
Injection site pain	n (%)	1 (5.9)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_15

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) [1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Related to Study Drug	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Endophthalmitis	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_16

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	4 (23.5)	6 (35.3)	1.7727 (0.3962, 7.9324)	1.5000 (0.5136, 4.3808)	0.1176 (-0.1861, 0.4214) 0.4583
Eye disorders	n (%)	3 (17.6)	6 (35.3)	-	-	-
Conjunctival haemorrhage	n (%)	0	3 (17.6)	-	-	-
Eye pain	n (%)	0	2 (11.8)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_16

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) [1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Eye disorders						
Blindness transient	n (%)	0	1 (5.9)	-	-	-
				-	-	-
Keratopathy	n (%)	0	1 (5.9)	-	-	-
				-	-	-
Abnormal sensation in eye	n (%)	1 (5.9)	0	-	-	-
				-	-	-
Cataract	n (%)	1 (5.9)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_16

DATE: 16JUL2024 5:37

Table Saf_16

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) [1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Lacrimation increased	n (%)	1 (5.9)	0	-	-	-	-
				-	-	-	-
Investigations	n (%)	1 (5.9)	1 (5.9)	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	1 (5.9)	1 (5.9)	-	-	-	-
				-	-	-	-
General disorders and administration site conditions	n (%)	1 (5.9)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_16

DATE: 16JUL2024 5:37

Table Saf_16

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain	n (%)	1 (5.9)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_16

DATE: 16JUL2024 5:37

Table Saf_16

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	3 (23.1)	3 (21.4)	0.9091 (0.1480, 5.5830)	0.9286 (0.2265, 3.8074)	-0.0165 (-0.3306, 0.2976) 0.9195
Eye disorders	n (%)	2 (15.4)	2 (14.3)	-	-	-
Conjunctival haemorrhage	n (%)	2 (15.4)	1 (7.1)	-	-	-
Corneal scar	n (%)	0	1 (7.1)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_16

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders						
Punctate keratitis	n (%)	0	1 (7.1)	- -	- -	- -
Infections and infestations	n (%)	0	1 (7.1)	- -	- -	- -
Endophthalmitis	n (%)	0	1 (7.1)	- -	- -	- -
General disorders and administration site conditions	n (%)	1 (7.7)	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_16

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study
(Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain	n (%)	1 (7.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_16

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Table Saf_16

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1
Study
(Safety Population)

MedDRA System Organ Class

MedDRA Preferred Term

At Least 1 TEAE Related to Either Study Drug or Study Medication Administration
Procedure

Statistic

p-value [3]

Interaction

0.5113

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_16

DATE: 16JUL2024 5:37

Table Saf_17

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE Related to Study Drug	n (%)	0	1 (5.9)	-	-	-
Eye disorders	n (%)	0	1 (5.9)	-	-	-
Blindness transient	n (%)	0	1 (5.9)	-	-	-
Investigations	n (%)	0	1 (5.9)	-	-	-
Intraocular pressure increased	n (%)	0	1 (5.9)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_17

DATE: 12JUL2024 6:31

Table Saf_17

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

>= 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
At Least 1 Serious TEAE Related to Study Drug	n (%)	0	1 (7.1)	-	-	-
				-	-	-
Infections and infestations	n (%)	0	1 (7.1)	-	-	-
				-	-	-
Endophthalmitis	n (%)	0	1 (7.1)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_18

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious TEAE Related to Study Medication Administration Procedure	n (%)	0	1 (5.9)	-	-	-	-
Eye disorders	n (%)	0	1 (5.9)	-	-	-	-
Blindness transient	n (%)	0	1 (5.9)	-	-	-	-
Investigations	n (%)	0	1 (5.9)	-	-	-	-
Intraocular pressure increased	n (%)	0	1 (5.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_18

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious TEAE Related to Study Medication Administration Procedure	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Endophthalmitis	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_19

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

< 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) [1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	0	1 (5.9)	-	-	-
Eye disorders	n (%)	0	1 (5.9)	-	-	-
Blindness transient	n (%)	0	1 (5.9)	-	-	-
Investigations	n (%)	0	1 (5.9)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_19

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in
NORSE-1 Study
(Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Investigations							
Intraocular pressure increased	n (%)	0	1 (5.9)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_19

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

>= 80 years

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) [1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	0	1 (7.1)	- -	- -	- -
Infections and infestations	n (%)	0	1 (7.1)	- -	- -	- -
Endophthalmitis	n (%)	0	1 (7.1)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
At Least 1 TEAE		n (%)	13 (76.5)	14 (82.4)	1.4359 (0.2685, 7.6777)	1.0769 (0.7639, 1.5182)	0.0588 (-0.2123, 0.3299)	0.6761
Eye disorders	Grade 1	n (%)	3 (17.6)	7 (41.2)	3.2667 (0.6747, 15.8164)	2.3333 (0.7216, 7.5451)	0.2353 (-0.0606, 0.5312)	0.1380
	Grade 2	n (%)	2 (11.8)	2 (11.8)	-	-	-	-
	Grade 3	n (%)	1 (5.9)	1 (5.9)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	0	3 (17.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

< 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Eye pain	Grade 1	n (%)	0	2 (11.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	2 (11.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blepharitis	Grade 1	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blindness transient	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Keratopathy	Grade 1	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lenticular opacities	Grade 1	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Seasonal allergy	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (5.9)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Subretinal fluid	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (5.9)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous detachment	Grade 1	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Abnormal sensation in eye	Grade 1	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cataract	Grade 1	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Neovascular age-related macular degeneration	Grade 1	n (%)	0	0	-	-	-
					-	-	-
					-	-	-
	Grade 2	n (%)	1 (5.9)	0	-	-	-
					-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)						
Investigations	Grade 1	n (%)	4 (23.5)	4 (23.5)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (5.9)	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	1 (5.9)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	3 (17.6)	2 (11.8)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	1 (5.9)	1 (5.9)	-	-	-
triglycerides					-	-	-
increased	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea increased	Grade 1	n (%)	2 (11.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Eosinophil count increased	Grade 1	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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< 80 years							
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Investigations							
Platelet	Grade 1	n (%)	0	1 (5.9)	-	-	-
morphology					-	-	-
abnormal	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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< 80 years							
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Investigations							
Blood	Grade 1	n (%)	1 (5.9)	0	-	-	-
creatinine							
increased	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood sodium increased	Grade 1	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

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Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Protein urine present	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations	Grade 1	n (%)	2 (11.8)	2 (11.8)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	2 (11.8)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Tooth infection	Grade 1	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Conjunctivitis	Grade 1	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Influenza	Grade 1	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Blood and lymphatic system disorders	Grade 1	n (%)	0	2 (11.8)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Lymphadenopathy	Grade 1	n (%)	0	1 (5.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Macrocytosis	Grade 1	n (%)	0	1 (5.9)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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< 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade							
Gastrointestinal disorders	Grade 1	n (%)	1 (5.9)	1 (5.9)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Pancreatitis	Grade 1	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Tooth abscess	Grade 1	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (5.9)	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (5.9)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Ankle fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

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Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Endocrine disorders	Grade 1	n (%)	0	1 (5.9)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Endocrine disorders							
Hyperthyroidism	Grade 1	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Metabolism and nutrition disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	1 (5.9)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypercholesterolemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Type 2 diabetes mellitus	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Renal and urinary disorders	Grade 1	n (%)	0	1 (5.9)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Glycosuria	Grade 1	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
General disorders and administration site conditions	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (5.9)	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-
					-	-	-	-
					-	-	-	-
					-	-	-	-
					-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	1 (5.9)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Contusion	Grade 1	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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< 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (5.9)	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Insomnia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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< 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)						
Vascular disorders	Grade 1	n (%)	1 (5.9)	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

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< 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypertension	Grade 1	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
At Least 1 TEAE		n (%)	7 (53.8)	11 (78.6)	3.1429 (0.5864, 16.8448)	1.4592 (0.8229, 2.5875)	0.2473 (-0.0986, 0.5931)	0.1814
Eye disorders	Grade 1	n (%)	4 (30.8)	3 (21.4)	0.6136 (0.1080, 3.4854)	0.6964 (0.1912, 2.5367)	-0.0934 (-0.4238, 0.2370)	0.5871
	Grade 2	n (%)	2 (15.4)	2 (14.3)	-	-	-	-
	Grade 3	n (%)	0	1 (7.1)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	2 (15.4)	2 (14.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Posterior capsule opacification	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	2 (14.3)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	2 (15.4)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Choroidal neovascularisation	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctivitis allergic	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Corneal scar	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Dry eye	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Punctate keratitis	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Visual impairment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blepharitis	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Diabetic retinal oedema	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Neovascular age-related macular degeneration	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Scleromalacia	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade	n (%)					
Investigations	Grade 1	n (%)	3 (23.1)	4 (28.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	1 (7.7)	2 (14.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	0	2 (14.3)	-	-	-
creatinine					-	-	-
increased	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea increased	Grade 1	n (%)	1 (7.7)	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 5:38

>= 80 years

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Blood albumin increased	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure systolic increased	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Protein urine present	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cell rouleaux formation present	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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DATE: 16JUL2024 5:38

>= 80 years

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Red blood cells urine positive	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Urinary casts	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Aspartate aminotransferase increased	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood glucose increased	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood lactate dehydrogenase increased	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Eosinophil count increased	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Platelet count decreased	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations	Grade 1	n (%)	1 (7.7)	2 (14.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Influenza	Grade 1	n (%)	1 (7.7)	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Candida infection	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 5:38

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Endophthalmitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Kidney infection	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	1 (7.7)	1 (7.1)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (7.7)	1 (7.1)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	1 (7.7)	0	- -	- -	- -
	Grade 2	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Rheumatoid arthritis	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Wrist fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade							
Gastrointestinal disorders	Grade 1	n (%)	1 (7.7)	1 (7.1)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Diarrhoea	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Vomiting	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (7.7)	1 (7.1)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Basal cell carcinoma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (7.7)	1 (7.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	2 (15.4)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders Brow ptosis	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Skin laceration	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Immune system disorders	Grade 1	n (%)	0	1 (7.1)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Seasonal allergy	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	0	1 (7.1)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Macular scar	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	1 (7.1)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Confusional state	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (7.1)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Renal and urinary disorders	Grade 1	n (%)	0	1 (7.1)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Renal tubular acidosis	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Vascular disorders	Grade 1	n (%)	0	1 (7.1)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Dizziness	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
General disorders and administration site conditions	Grade 1	n (%)	1 (7.7)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

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Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain	Grade 1	n (%)	1 (7.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Date of data extract: 26AUG2020

Table Saf_20

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age Group in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic p-value [3]	Interaction
At Least 1 TEAE			0.5113
Eye disorders	Grade 1	p-value [3]	0.1368

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_20

DATE: 16JUL2024 5:38

Table Saf_21

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age in NORSE-1 Study Group (Safety Population)

< 80 years								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value	
At Least 1 Serious TEAE		n (%)	2 (11.8)	1 (5.9)	-	-	-	-
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (5.9)	0	-	-	-	-
	Grade 3	n (%)	1 (5.9)	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-
					-	-	-	-
					-	-	-	-
					-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_21

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Table Saf_21

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age in NORSE-1 Study Group (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Musculoskeletal and connective tissue disorders	Ankle fracture	Grade 1 n (%)	0	0	-	-	-
					-	-	-
		Grade 2 n (%)	1 (5.9)	0	-	-	-
					-	-	-
		Grade 3 n (%)	0	0	-	-	-
					-	-	-
		Grade 4 n (%)	0	0	-	-	-
					-	-	-
		Grade 5 n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_21

DATE: 15JUL2024 5:02

Table Saf_21

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age in NORSE-1 Study Group (Safety Population)

< 80 years							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Musculoskeletal and connective tissue disorders Back pain							
	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (5.9)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_21

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age in NORSE-1 Study Group (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) [1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_21

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age in NORSE-1 Study Group (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders							
Blindness transient	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_21

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age in NORSE-1 Study Group (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) [1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (5.9)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_21

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age in NORSE-1 Study Group (Safety Population)

< 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations							
Intraocular pressure increased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (5.9)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_21

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Table Saf_21

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age in NORSE-1 Study Group (Safety Population)

>= 80 years								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value	
At Least 1 Serious TEAE		n (%)	0	3 (21.4)	-	-	-	-
Infections and infestations	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	1 (7.1)	-	-	-	-
	Grade 3	n (%)	0	1 (7.1)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

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Table Saf_21

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age in NORSE-1 Study Group (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations							
Endophthalmitis	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (7.1)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_21

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age in NORSE-1 Study Group (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_21

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Table Saf_21

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age in NORSE-1 Study Group (Safety Population)

>= 80 years							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data) [1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_21

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Age in NORSE-1 Study Group (Safety Population)

>= 80 years							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders							
Visual impairment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_21

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Table Saf_22

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

< 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data) (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	1 (5.9)	2 (11.8)	-	-	-	-
				-	-	-	-
Eye disorders	n (%)	1 (5.9)	2 (11.8)	-	-	-	-
				-	-	-	-
Visual acuity reduced	n (%)	1 (5.9)	1 (5.9)	-	-	-	-
				-	-	-	-
Subretinal fluid	n (%)	0	1 (5.9)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_22

DATE: 13JUL2024 17:48

Table Saf_22

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

>= 80 years						
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	2 (15.4)	1 (7.1)	-	-	-
Eye disorders	n (%)	2 (15.4)	0	-	-	-
Visual acuity reduced	n (%)	2 (15.4)	0	-	-	-
Infections and infestations	n (%)	0	1 (7.1)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_22

DATE: 13JUL2024 17:48

Table Saf_22

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Age Group in NORSE-1 Study (Safety Population)

>= 80 years							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Infections and infestations							
Endophthalmitis	n (%)	0	1 (7.1)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_22

DATE: 13JUL2024 17:48

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

		Male					
MedDRA System Organ Class		ONS-5010		Odds Ratio		Relative Risk	
MedDRA Preferred Term		Ranibizumab (N=15)	(Masked Data) (N=9)	95% CI		95% CI	
Statistic		[1]					
At Least 1 TEAE		n (%)		3.0625		1.4583	
		8 (53.3)		(0.4718, 19.8788)		(0.8098, 2.6262)	
						0.2444	
						95% CI	
						p-value[2]	
Eye disorders		n (%)		0.9143		0.9524	
		7 (46.7)		(0.1737, 4.8114)		(0.3838, 2.3636)	
						-0.0222	
						(-0.4335, 0.3890)	
						0.9175	
Conjunctival haemorrhage		n (%)		-		-	
		1 (6.7)		-		-	
Visual acuity reduced		n (%)		-		-	
		3 (20.0)		-		-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_23

DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Corneal scar	n (%)	0	1 (11.1)	-	-	-	-
				-	-	-	-
Punctate keratitis	n (%)	0	1 (11.1)	-	-	-	-
				-	-	-	-
Abnormal sensation in eye	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Cataract	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_23

DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Lacrimation increased	n (%)	1 (6.7)	0	-	-		-
				-	-		-
Neovascular age-related macular degeneration	n (%)	1 (6.7)	0	-	-		-
				-	-		-
Investigations	n (%)	3 (20.0)	2 (22.2)	1.1429 (0.1520, 8.5933)	1.1111 (0.2273, 5.4318)		0.0222 (-0.3165, 0.3610)
Eosinophil count increased	n (%)	1 (6.7)	1 (11.1)	-	-		0.8989
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood triglycerides increased	n (%)	0	1 (11.1)	-	-	-	-
Platelet morphology abnormal	n (%)	0	1 (11.1)	-	-	-	-
Aspartate aminotransferase increased	n (%)	1 (6.7)	0	-	-	-	-
Blood glucose increased	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood lactate dehydrogenase increased	n (%)	1 (6.7)	0	-	-	-	-
Blood urea increased	n (%)	1 (6.7)	0	-	-	-	-
Intraocular pressure increased	n (%)	1 (6.7)	0	-	-	-	-
Platelet count decreased	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Male						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=9)			
Infections and infestations	n (%)	2 (13.3)	1 (11.1)	- -	- -	- -
Influenza	n (%)	1 (6.7)	1 (11.1)	- -	- -	- -
Conjunctivitis	n (%)	1 (6.7)	0	- -	- -	- -
Lower respiratory tract infection	n (%)	1 (6.7)	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Blood and lymphatic system disorders	n (%)	0	1 (11.1)	-	-	-	-
Macrocytosis	n (%)	0	1 (11.1)	-	-	-	-
Gastrointestinal disorders	n (%)	0	1 (11.1)	-	-	-	-
Pancreatitis	n (%)	0	1 (11.1)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-	-
Injection site pain	n (%)	1 (6.7)	0	-	-	-	-
Injury, poisoning and procedural complications	n (%)	1 (6.7)	0	-	-	-	-
Contusion	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Male						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders	n (%)	1 (6.7)	0	-	-	-
Insomnia	n (%)	1 (6.7)	0	-	-	-
Skin and subcutaneous tissue disorders	n (%)	1 (6.7)	0	-	-	-
Skin laceration	n (%)	1 (6.7)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
At Least 1 TEAE	n (%)	12 (80.0)	18 (81.8)	1.1250 (0.2127, 5.9502)	1.0227 (0.7422, 1.4094)	0.0182 (-0.2406, 0.2769)	0.8912
Eye disorders	n (%)	5 (33.3)	12 (54.5)	2.4000 (0.6144, 9.3753)	1.6364 (0.7272, 3.6820)	0.2121 (-0.1044, 0.5287)	0.2099
Conjunctival haemorrhage	n (%)	1 (6.7)	2 (9.1)	-	-	-	-
Eye pain	n (%)	0	2 (9.1)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Posterior capsule opacification	n (%)	0	2 (9.1)	-	-	-	-
Blepharitis	n (%)	1 (6.7)	1 (4.5)	-	-	-	-
Visual acuity reduced	n (%)	1 (6.7)	1 (4.5)	-	-	-	-
Blindness transient	n (%)	0	1 (4.5)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Choroidal neovascularisation	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Conjunctivitis allergic	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Dry eye	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Keratopathy	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Lenticular opacities	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Seasonal allergy	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Subretinal fluid	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Visual impairment	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-

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DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Vitreous detachment	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Diabetic retinal oedema	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Neovascular age-related macular degeneration	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Scleromalacia	n (%)	1 (6.7)	0	-	-		-
				-	-		-
Investigations	n (%)	5 (33.3)	7 (31.8)	0.9333 (0.2304, 3.7812)	0.9545 (0.3723, 2.4472)		-0.0152 (-0.3230, 0.2927) 0.9240
White blood cells urine positive	n (%)	4 (26.7)	4 (18.2)	-	-		-
				-	-		-
Blood creatinine increased	n (%)	1 (6.7)	2 (9.1)	-	-		-
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_23

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood urea increased	n (%)	2 (13.3)	1 (4.5)	-	-	-	-
				-	-	-	-
Protein urine present	n (%)	1 (6.7)	1 (4.5)	-	-	-	-
				-	-	-	-
Blood albumin increased	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Blood pressure systolic increased	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Intraocular pressure increased	n (%)	0	1 (4.5)	-	-	-	-
Red blood cell rouleaux formation present	n (%)	0	1 (4.5)	-	-	-	-
Red blood cells urine positive	n (%)	0	1 (4.5)	-	-	-	-
Urinary casts	n (%)	0	1 (4.5)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_23

DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood sodium increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Blood triglycerides increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	1 (6.7)	5 (22.7)	-	-	-	-
				-	-	-	-
Urinary tract infection	n (%)	0	3 (13.6)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Infections and infestations							
Candida infection	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Endophthalmitis	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Kidney infection	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Lower respiratory tract infection	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Infections and infestations							
Tooth infection	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Influenza	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Musculoskeletal and connective tissue disorders	n (%)	4 (26.7)	2 (9.1)	-	-	-	-
				-	-	-	-
Back pain	n (%)	2 (13.3)	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value [2]
Musculoskeletal and connective tissue disorders							
Rheumatoid arthritis	n (%)	0	1 (4.5)	-	-		-
				-	-		-
Ankle fracture	n (%)	1 (6.7)	0	-	-		-
				-	-		-
Wrist fracture	n (%)	1 (6.7)	0	-	-		-
				-	-		-
Gastrointestinal disorders	n (%)	2 (13.3)	1 (4.5)	-	-		-
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Gastrointestinal disorders							
Diarrhoea	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Tooth abscess	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Vomiting	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Renal and urinary disorders	n (%)	0	2 (9.1)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders							
Glycosuria	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Renal tubular acidosis	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	1 (6.7)	1 (4.5)	-	-	-	-
				-	-	-	-
Basal cell carcinoma	n (%)	1 (6.7)	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Vascular disorders	n (%)	1 (6.7)	1 (4.5)	-	-	-	-
				-	-	-	-
Dizziness	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Hypertension	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Blood and lymphatic system disorders	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_23

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Blood and lymphatic system disorders							
Lymphadenopathy	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Endocrine disorders	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Hyperthyroidism	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Immune system disorders	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1]	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value [2]
Immune system disorders							
Seasonal allergy	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Injury, poisoning and procedural complications	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Macular scar	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Metabolism and nutrition disorders	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Metabolism and nutrition disorders							
	Hypercholesterolaemia	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Type 2 diabetes mellitus	n (%)	0	1 (4.5)	-	-	-
					-	-	-
Psychiatric disorders		n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Confusional state	n (%)	0	1 (4.5)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_23

DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-	-
Injection site pain	n (%)	1 (6.7)	0	-	-	-	-
Skin and subcutaneous tissue disorders	n (%)	1 (6.7)	0	-	-	-	-
Brow ptosis	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_23

DATE: 16JUL2024 5:38

Table Saf_23

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 TEAE	p-value [3]	0.4425
Eye disorders	p-value [3]	0.2908
Investigations	p-value [3]	0.8555

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_23

DATE: 16JUL2024 5:38

Table Saf_24

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious TEAE	n (%)	2 (13.3)	4 (18.2)	-	-	-	-
				-	-	-	-
Eye disorders	n (%)	0	2 (9.1)	-	-	-	-
				-	-	-	-
Blindness transient	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Visual impairment	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	2 (9.1)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_24

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Table Saf_24

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Infections and infestations							
Endophthalmitis	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Lower respiratory tract infection	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Musculoskeletal and connective tissue disorders	n (%)	2 (13.3)	0	-	-	-	-
				-	-	-	-
Ankle fracture	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Back pain	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_24

DATE: 10JUL2024 8:36

Table Saf_24

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
 (Safety Population)

Female						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations	n (%)	0	1 (4.5)	-	-	-
				-	-	-
Intraocular pressure increased	n (%)	0	1 (4.5)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_24

DATE: 10JUL2024 8:36

Table Saf_25

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender
in NORSE-1 Study
(Safety Population)

Male						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=9)			
At Least 1 TEAE Related to Study Medication Administration Procedure	n (%)	4 (26.7)	4 (44.4)	- -	- -	- -
Eye disorders	n (%)	2 (13.3)	4 (44.4)	- -	- -	- -
Conjunctival haemorrhage	n (%)	1 (6.7)	3 (33.3)	- -	- -	- -
Corneal scar	n (%)	0	1 (11.1)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_25

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender
in NORSE-1 Study
(Safety Population)

Male						
MedDRA System Organ Class		Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic					
Eye disorders						
Punctate keratitis	n (%)	0	1 (11.1)	-	-	-
				-	-	-
Abnormal sensation in eye	n (%)	1 (6.7)	0	-	-	-
				-	-	-
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-
				-	-	-
Injection site pain	n (%)	1 (6.7)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_25

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender
in NORSE-1 Study
(Safety Population)

Male						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=9)			
Investigations	n (%)	1 (6.7)	0	-	-	-
				-	-	-
Intraocular pressure increased	n (%)	1 (6.7)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_25

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender
in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Related to Study Medication Administration Procedure	n (%)	2 (13.3)	5 (22.7)	-	-	-	-
Eye disorders	n (%)	2 (13.3)	4 (18.2)	-	-	-	-
Eye pain	n (%)	0	2 (9.1)	-	-	-	-
Conjunctival haemorrhage	n (%)	1 (6.7)	1 (4.5)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_25

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender
in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Eye disorders							
Blindness transient	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Keratopathy	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_25

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender
in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
MedDRA Preferred Term							
Infections and infestations							
Endophthalmitis	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Investigations	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_25

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender
in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
General disorders and administration site conditions							
Injection site pain	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_26

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in
NORSE-1 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Related to Study Drug	n (%)	3 (20.0)	0	-	-	-	-
Eye disorders	n (%)	2 (13.3)	0	-	-	-	-
Abnormal sensation in eye	n (%)	1 (6.7)	0	-	-	-	-
Cataract	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_26

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Male						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations	n (%)	1 (6.7)	0	-	-	-
Intraocular pressure increased	n (%)	1 (6.7)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_26

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female						
MedDRA System Organ Class		Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic					
At Least 1 TEAE Related to Study Drug	n (%)	1 (6.7)	3 (13.6)	-	-	-
				-	-	-
Eye disorders	n (%)	1 (6.7)	2 (9.1)	-	-	-
				-	-	-
Blindness transient	n (%)	0	1 (4.5)	-	-	-
				-	-	-
Eye pain	n (%)	0	1 (4.5)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_26

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Table Saf_26

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Eye disorders						
Lacrimation increased	n (%)	1 (6.7)	0	-	-	-
				-	-	-
Infections and infestations	n (%)	0	1 (4.5)	-	-	-
				-	-	-
Endophthalmitis	n (%)	0	1 (4.5)	-	-	-
				-	-	-
Investigations	n (%)	0	1 (4.5)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_26

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in
NORSE-1 Study
(Safety Population)

Female						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations						
Intraocular pressure increased	n (%)	0	1 (4.5)	-	-	-
				-	-	-
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-
				-	-	-
Injection site pain	n (%)	1 (6.7)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_27

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	5 (33.3)	4 (44.4)	-	-	-	-
Eye disorders	n (%)	3 (20.0)	4 (44.4)	-	-	-	-
Conjunctival haemorrhage	n (%)	1 (6.7)	3 (33.3)	-	-	-	-
Corneal scar	n (%)	0	1 (11.1)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_27

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Table Saf_27

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Eye disorders							
Punctate keratitis	n (%)	0	1 (11.1)	-	-	-	-
				-	-	-	-
Abnormal sensation in eye	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Cataract	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_27

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
General disorders and administration site conditions							
Injection site pain	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Investigations	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_27

DATE: 11JUL2024 15:12

Table Saf_27

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	2 (13.3)	5 (22.7)	-	-	-	-
Eye disorders	n (%)	2 (13.3)	4 (18.2)	-	-	-	-
Eye pain	n (%)	0	2 (9.1)	-	-	-	-
Conjunctival haemorrhage	n (%)	1 (6.7)	1 (4.5)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_27

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Eye disorders							
Blindness transient	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Keratopathy	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_27

DATE: 11JUL2024 15:12

Table Saf_27

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Infections and infestations							
Endophthalmitis	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Investigations	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_27

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study
(Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
General disorders and administration site conditions							
Injection site pain	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_28

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
At Least 1 Serious TEAE Related to Study Drug	n (%)	0	2 (9.1)	-	-	-
				-	-	-
Eye disorders	n (%)	0	1 (4.5)	-	-	-
				-	-	-
Blindness transient	n (%)	0	1 (4.5)	-	-	-
				-	-	-
Infections and infestations	n (%)	0	1 (4.5)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_28

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
MedDRA Preferred Term							
Infections and infestations							
Endophthalmitis	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Investigations	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_29

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
At Least 1 Serious TEAE Related to Study Medication Administration Procedure	n (%)	0	2 (9.1)	-	-	-
Eye disorders	n (%)	0	1 (4.5)	-	-	-
Blindness transient	n (%)	0	1 (4.5)	-	-	-
Infections and infestations	n (%)	0	1 (4.5)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_29

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
MedDRA Preferred Term							
Infections and infestations							
Endophthalmitis	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Investigations	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_30

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	0	2 (9.1)	-	-	-
Eye disorders	n (%)	0	1 (4.5)	-	-	-
Blindness transient	n (%)	0	1 (4.5)	-	-	-
Infections and infestations	n (%)	0	1 (4.5)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_30

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Gender in
NORSE-1 Study
(Safety Population)

Female						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Infections and infestations						
Endophthalmitis	n (%)	0	1 (4.5)	-	-	-
				-	-	-
Investigations	n (%)	0	1 (4.5)	-	-	-
				-	-	-
Intraocular pressure increased	n (%)	0	1 (4.5)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE		n (%)	8 (53.3)	7 (77.8)	3.0625 (0.4718, 19.8788)	1.4583 (0.8098, 2.6262)	0.2444 (-0.1264, 0.6153) 0.2411
Eye disorders	Grade 1	n (%)	3 (20.0)	3 (33.3)	2.0000 (0.3062, 13.0615)	1.6667 (0.4233, 6.5617)	0.1333 (-0.2352, 0.5019) 0.4747
	Grade 2	n (%)	3 (20.0)	1 (11.1)	-	-	-
	Grade 3	n (%)	1 (6.7)	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	1 (6.7)	3 (33.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	2 (13.3)	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=15)	(N=9)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Corneal scar	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (11.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Punctate keratitis	Grade 1	n (%)	0	1 (11.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Abnormal sensation in eye	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cataract	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Neovascular age-related macular degeneration	Grade 1	n (%)	0	0	-	-	-
					-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	Grade 1	n (%)	3 (20.0)	2 (22.2)	1.1429 (0.1520, 8.5933)	1.1111 (0.2273, 5.4318)	0.0222 (-0.3165, 0.3610) 0.8989
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Eosinophil count increased	Grade 1	n (%)	1 (6.7)	1 (11.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	0	1 (11.1)	-	-	-
triglycerides							
increased	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Platelet morphology abnormal	Grade 1	n (%)	0	1 (11.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Aspartate aminotransferase increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood glucose increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood lactate dehydrogenase increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Male							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=15)	(N=9)	95% CI	95% CI	Difference 95% CI p-value[2]
Investigations							
Platelet count decreased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade							
Infections and infestations	Grade 1	n (%)	2 (13.3)	1 (11.1)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Influenza	Grade 1	n (%)	1 (6.7)	1 (11.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 5:39

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Conjunctivitis	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade	n (%)					
Blood and lymphatic system disorders	Grade 1	n (%)	0	1 (11.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Macrocytosis	Grade 1	n (%)	0	1 (11.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade							
Gastrointestinal disorders	Grade 1	n (%)	0	1 (11.1)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Pancreatitis	Grade 1	n (%)	0	1 (11.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
General disorders and administration site conditions	Grade 1	n (%)	1 (6.7)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	1 (6.7)	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Contusion	Grade 1	n (%)	1 (6.7)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Insomnia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	1 (6.7)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Male							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Skin laceration	Grade 1	n (%)	1 (6.7)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
At Least 1 TEAE		n (%)	12 (80.0)	18 (81.8)	1.1250 (0.2127, 5.9502)	1.0227 (0.7422, 1.4094)	0.0182 (-0.2406, 0.2769)	0.8912
Eye disorders	Grade 1	n (%)	4 (26.7)	7 (31.8)	1.2833 (0.2998, 5.4936)	1.1932 (0.4224, 3.3706)	0.0515 (-0.2451, 0.3481)	0.7399
	Grade 2	n (%)	1 (6.7)	3 (13.6)	-	-	-	-
	Grade 3	n (%)	0	2 (9.1)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	1 (6.7)	2 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Eye pain	Grade 1	n (%)	0	2 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Posterior capsule opacification	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	2 (9.1)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Blepharitis	Grade 1	n (%)	1 (6.7)	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Blindness	Grade 1	n (%)	0	0	-	-	-
transient					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Choroidal neovascularisation	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Conjunctivitis allergic	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=15)	(N=22)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Dry eye	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=15)	(N=22)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Keratopathy	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lenticular opacities	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=15)	(N=22)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Seasonal allergy	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=15)	(N=22)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Subretinal fluid	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Visual impairment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk Difference
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=15)	(N=22)	95% CI	95% CI	95% CI p-value[2]
Eye disorders							
Vitreous detachment	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Diabetic retinal oedema	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=15)	(N=22)	95% CI	95% CI	Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Neovascular age-related macular degeneration	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Scleromalacia	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	Grade 1	n (%)	4 (26.7)	6 (27.3)	1.0313 (0.2348, 4.5295)	1.0227 (0.3468, 3.0165)	0.0061 (-0.2850, 0.2971) 0.9679
	Grade 2	n (%)	1 (6.7)	0	-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	4 (26.7)	4 (18.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	1 (6.7)	2 (9.1)	-	-	-
creatinine					-	-	-
increased	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea increased	Grade 1	n (%)	2 (13.3)	1 (4.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Investigations							
Protein urine present	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE			ONS-5010 (Masked Data)[1]	Odds Ratio	Relative Risk	Absolute Risk
MedDRA Preferred Term	Grade	Statistic	Ranibizumab (N=15)	(N=22)	95% CI	95% CI	Difference 95% CI p-value[2]
Investigations							
Blood albumin increased	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure systolic increased	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cell rouleaux formation present	Grade 1	n (%)	0	1 (4.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cells urine positive	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Urinary casts	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood sodium increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	1 (6.7)	0	-	-	-
triglycerides							
increased	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations	Grade 1	n (%)	1 (6.7)	3 (13.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	3 (13.6)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Candida infection	Grade 1	n (%)	0	1 (4.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Endophthalmitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Kidney infection	Grade 1	n (%)	0	1 (4.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Tooth infection	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Influenza	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	1 (6.7)	1 (4.5)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	2 (13.3)	1 (4.5)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (6.7)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 3	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Musculoskeletal and connective tissue disorders							
Rheumatoid arthritis	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Musculoskeletal and connective tissue disorders							
Ankle fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Musculoskeletal and connective tissue disorders							
Wrist fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders	Grade 1	n (%)	2 (13.3)	1 (4.5)	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Diarrhoea	Grade 1	n (%)	0	1 (4.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders	Grade						
Tooth abscess	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Gastrointestinal disorders							
Vomiting	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Renal and urinary disorders	Grade 1	n (%)	0	2 (9.1)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Renal and urinary disorders							
Glycosuria	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Renal tubular acidosis	Grade 1	n (%)	0	1 (4.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (6.7)	1 (4.5)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Basal cell carcinoma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	1 (4.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)						
Vascular disorders	Grade 1	n (%)	1 (6.7)	1 (4.5)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Dizziness	Grade 1	n (%)	0	1 (4.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypertension	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)						
Blood and lymphatic system disorders	Grade 1	n (%)	0	1 (4.5)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Lymphadenopathy	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade							
Endocrine disorders	Grade 1	n (%)	0	1 (4.5)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Endocrine disorders							
Hyperthyroidism	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Immune system disorders	Grade 1	n (%)	0	1 (4.5)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Seasonal allergy	Grade 1	n (%)	0	1 (4.5)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	0	1 (4.5)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Macular scar	Grade 1	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Metabolism and nutrition disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 5:39

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypercholesterolemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Type 2 diabetes mellitus	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	1 (4.5)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Confusional state	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	1 (4.5)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
General disorders and administration site conditions	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	1 (6.7)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Brow ptosis	Grade 1	n (%)	1 (6.7)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 5:39

Date of data extract: 26AUG2020

Table Saf_31

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic p-value [3]	Interaction
At Least 1 TEAE			0.4425
Eye disorders	Grade 1	p-value [3]	0.8555
Investigations	Grade 1	p-value [3]	0.9522

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.
[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_31

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Table Saf_32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE		n (%)	2 (13.3)	4 (18.2)	-	-	-
Eye disorders	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	2 (9.1)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_32

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Table Saf_32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders							
Blindness transient	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders							
Visual impairment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations	Endophthalmitis	Grade 1	n (%)	0	0	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_32

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Table Saf_32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_32

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Table Saf_32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_32

DATE: 15JUL2024 5:06

Table Saf_32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female								Absolute Risk Difference 95% CI p-value
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		
Musculoskeletal and connective tissue disorders								
Ankle fracture	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_32

DATE: 15JUL2024 5:06

Table Saf_32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Musculoskeletal and connective tissue disorders Back pain							
	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_32

DATE: 15JUL2024 5:06

Table Saf_32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_32

DATE: 15JUL2024 5:06

Table Saf_32

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Gender in NORSE-1 Study (Safety Population)

Female							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations							
Intraocular pressure increased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.5)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_32

DATE: 15JUL2024 5:06

Table Saf_33

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Male							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	2 (13.3)	0	-	-	-	-
Eye disorders	n (%)	2 (13.3)	0	-	-	-	-
Visual acuity reduced	n (%)	2 (13.3)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_33

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Table Saf_33

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	1 (6.7)	3 (13.6)	-	-	-	-
				-	-	-	-
Eye disorders	n (%)	1 (6.7)	2 (9.1)	-	-	-	-
				-	-	-	-
Visual acuity reduced	n (%)	1 (6.7)	1 (4.5)	-	-	-	-
				-	-	-	-
Subretinal fluid	n (%)	0	1 (4.5)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_33

DATE: 14JUL2024 6:56

Table Saf_33

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Gender in NORSE-1 Study (Safety Population)

Female						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=22)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations	n (%)	0	1 (4.5)	-	-	-
Endophthalmitis	n (%)	0	1 (4.5)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_33

DATE: 14JUL2024 6:56

Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class		ONS-5010					Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Risk	Difference 95% CI p-value[2]
At Least 1 TEAE	n (%)	7 (46.7)	20 (80.0)	4.5714 (1.1156, 18.7325)	1.7143 (0.9642, 3.0478)		0.3333 (0.0361,0.6305) 0.0314
Eye disorders	n (%)	5 (33.3)	13 (52.0)	2.1667 (0.5732, 8.1897)	1.5600 (0.6949, 3.5023)		0.1867 (-0.1220,0.4953) 0.2566
Conjunctival haemorrhage	n (%)	1 (6.7)	4 (16.0)	-	-		-
				-	-		-
Eye pain	n (%)	0	2 (8.0)	-	-		-
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Posterior capsule opacification	n (%)	0	2 (8.0)	-	-	-	-
Blepharitis	n (%)	1 (6.7)	1 (4.0)	-	-	-	-
Visual acuity reduced	n (%)	1 (6.7)	1 (4.0)	-	-	-	-
Corneal scar	n (%)	0	1 (4.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Dry eye	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Keratopathy	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Lenticular opacities	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Punctate keratitis	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Subretinal fluid	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Visual impairment	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Vitreous detachment	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Abnormal sensation in eye	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Cataract	n (%)	1 (6.7)	0	-	-		-
				-	-		-
Lacrimation increased	n (%)	1 (6.7)	0	-	-		-
				-	-		-
Scleromalacia	n (%)	1 (6.7)	0	-	-		-
				-	-		-
Investigations	n (%)	1 (6.7)	7 (28.0)	-	-		-
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

DATE: 16JUL2024 5:39

Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
White blood cells urine positive	n (%)	1 (6.7)	4 (16.0)	-	-	-	-
Blood creatinine increased	n (%)	0	2 (8.0)	-	-	-	-
Protein urine present	n (%)	1 (6.7)	1 (4.0)	-	-	-	-
Blood albumin increased	n (%)	0	1 (4.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

DATE: 16JUL2024 5:39

Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood pressure systolic increased	n (%)	0	1 (4.0)	-	-	-	-
Blood urea increased	n (%)	0	1 (4.0)	-	-	-	-
Platelet morphology abnormal	n (%)	0	1 (4.0)	-	-	-	-
Red blood cell rouleaux formation present	n (%)	0	1 (4.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Red blood cells urine positive	n (%)	0	1 (4.0)	-	-	-	-
Urinary casts	n (%)	0	1 (4.0)	-	-	-	-
Infections and infestations	n (%)	0	5 (20.0)	-	-	-	-
Urinary tract infection	n (%)	0	2 (8.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

DATE: 16JUL2024 5:39

Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Infections and infestations							
Candida infection	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Endophthalmitis	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Influenza	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Kidney infection	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Infections and infestations							
Lower respiratory tract infection	n (%)	0	1 (4.0)	-	-	-	
				-	-	-	
Tooth infection	n (%)	0	1 (4.0)	-	-	-	
				-	-	-	
Musculoskeletal and connective tissue disorders							
Back pain	n (%)	1 (6.7)	2 (8.0)	-	-	-	
				-	-	-	
Back pain	n (%)	1 (6.7)	1 (4.0)	-	-	-	
				-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Rheumatoid arthritis	n (%)	0	1 (4.0)	-	-	-	-
Blood and lymphatic system disorders	n (%)	0	2 (8.0)	-	-	-	-
Lymphadenopathy	n (%)	0	1 (4.0)	-	-	-	-
Macrocytosis	n (%)	0	1 (4.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Renal and urinary disorders	n (%)	0	2 (8.0)	-	-	-	-
Glycosuria	n (%)	0	1 (4.0)	-	-	-	-
Renal tubular acidosis	n (%)	0	1 (4.0)	-	-	-	-
Injury, poisoning and procedural complications	n (%)	1 (6.7)	1 (4.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Injury, poisoning and procedural complications							
Macular scar	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Contusion	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	1 (6.7)	1 (4.0)	-	-	-	-
				-	-	-	-
Basal cell carcinoma	n (%)	1 (6.7)	1 (4.0)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Gastrointestinal disorders	n (%)	0	1 (4.0)	-	-	-	-
Diarrhoea	n (%)	0	1 (4.0)	-	-	-	-
Immune system disorders	n (%)	0	1 (4.0)	-	-	-	-
Seasonal allergy	n (%)	0	1 (4.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Metabolism and nutrition disorders	n (%)	0	1 (4.0)	-	-	-	-
Hypercholesterolaemia	n (%)	0	1 (4.0)	-	-	-	-
Type 2 diabetes mellitus	n (%)	0	1 (4.0)	-	-	-	-
Psychiatric disorders	n (%)	0	1 (4.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Psychiatric disorders							
Confusional state	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Vascular disorders	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Dizziness	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Skin and subcutaneous tissue disorders	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Brow ptosis	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
At Least 1 TEAE	n (%)	13 (86.7)	5 (83.3)	0.7692 (0.0564, 10.4886)	0.9615 (0.6386, 1.4477)	-0.0333 (-0.3776, 0.3109)	0.8474
Eye disorders	n (%)	7 (46.7)	3 (50.0)	1.1429 (0.1718, 7.6007)	1.0714 (0.4078, 2.8148)	0.0333 (-0.4397, 0.5064)	0.8927
Visual acuity reduced	n (%)	3 (20.0)	0	-	-	-	-
Conjunctival haemorrhage	n (%)	1 (6.7)	1 (16.7)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Neovascular age-related macular degeneration	n (%)	2 (13.3)	0	-	-	-	-
Blindness transient	n (%)	0	1 (16.7)	-	-	-	-
Choroidal neovascularisation	n (%)	0	1 (16.7)	-	-	-	-
Conjunctivitis allergic	n (%)	0	1 (16.7)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Seasonal allergy	n (%)	0	1 (16.7)	-	-	-	-
				-	-	-	-
Diabetic retinal oedema	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Investigations	n (%)	7 (46.7)	2 (33.3)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood urea increased	n (%)	3 (20.0)	0	-	-	-	-
				-	-	-	-
White blood cells urine positive	n (%)	3 (20.0)	0	-	-	-	-
				-	-	-	-
Blood triglycerides increased	n (%)	1 (6.7)	1 (16.7)	-	-	-	-
				-	-	-	-
Eosinophil count increased	n (%)	1 (6.7)	1 (16.7)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Intraocular pressure increased	n (%)	1 (6.7)	1 (16.7)	-	-	-	-
				-	-	-	-
Aspartate aminotransferase increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Blood creatinine increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Blood glucose increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood lactate dehydrogenase increased	n (%)	1 (6.7)	0	-	-	-	-
Blood sodium increased	n (%)	1 (6.7)	0	-	-	-	-
Platelet count decreased	n (%)	1 (6.7)	0	-	-	-	-
Infections and infestations	n (%)	3 (20.0)	1 (16.7)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Infections and infestations							
Influenza	n (%)	2 (13.3)	0	-	-		-
				-	-		-
Urinary tract infection	n (%)	0	1 (16.7)	-	-		-
				-	-		-
Conjunctivitis	n (%)	1 (6.7)	0	-	-		-
				-	-		-
Lower respiratory tract infection	n (%)	1 (6.7)	0	-	-		-
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders	n (%)	2 (13.3)	1 (16.7)	-	-	-
Pancreatitis	n (%)	0	1 (16.7)	-	-	-
Tooth abscess	n (%)	1 (6.7)	0	-	-	-
Vomiting	n (%)	1 (6.7)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

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Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference	
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=6)			95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	n (%)	3 (20.0)	0	-	-	-	-
Ankle fracture	n (%)	1 (6.7)	0	-	-	-	-
Back pain	n (%)	1 (6.7)	0	-	-	-	-
Wrist fracture	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

DATE: 16JUL2024 5:39

Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Endocrine disorders	n (%)	0	1 (16.7)	-	-	-
Hyperthyroidism	n (%)	0	1 (16.7)	-	-	-
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-
Injection site pain	n (%)	1 (6.7)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

DATE: 16JUL2024 5:39

Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Psychiatric disorders	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Insomnia	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Skin and subcutaneous tissue disorders	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Skin laceration	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

DATE: 16JUL2024 5:39

Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value[2]
Vascular disorders	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Hypertension	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

DATE: 16JUL2024 5:39

Table Saf_34

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in
NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 TEAE	p-value [3]	0.0373
Eye disorders	p-value [3]	0.3769

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_34

DATE: 16JUL2024 5:39

Table Saf_35

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious TEAE	n (%)	1 (6.7)	3 (12.0)	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	2 (8.0)	-	-	-	-
				-	-	-	-
Endophthalmitis	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Lower respiratory tract infection	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Eye disorders	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_35

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Table Saf_35

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Eye disorders							
Visual impairment	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Musculoskeletal and connective tissue disorders	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Back pain	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_35

DATE: 10JUL2024 9:04

Table Saf_35

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=6)			
At Least 1 Serious TEAE	n (%)	1 (6.7)	1 (16.7)	-	-	-
				-	-	-
Eye disorders	n (%)	0	1 (16.7)	-	-	-
				-	-	-
Blindness transient	n (%)	0	1 (16.7)	-	-	-
				-	-	-
Investigations	n (%)	0	1 (16.7)	-	-	-
				-	-	-
Intraocular pressure increased	n (%)	0	1 (16.7)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_35

DATE: 10JUL2024 9:04

Table Saf_35

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=6)			
Musculoskeletal and connective tissue disorders	n (%)	1 (6.7)	0	-	-	-
Ankle fracture	n (%)	1 (6.7)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_35

DATE: 10JUL2024 9:04

Table Saf_36

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class		ONS-5010		Odds Ratio		Relative Risk	
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data) (N=25)	95% CI		95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE Related to Study Medication Administration Procedure	n (%)	3 (20.0)	8 (32.0)	1.8824 (0.4122, 8.5962)		1.6000 (0.5004, 5.1156)	0.1200 (-0.1528, 0.3928) 0.4165
Eye disorders	n (%)	3 (20.0)	7 (28.0)	1.5556 (0.3344, 7.2353)		1.4000 (0.4253, 4.6085)	0.0800 (-0.1882, 0.3482) 0.5765
Conjunctival haemorrhage	n (%)	1 (6.7)	4 (16.0)	-		-	-
Eye pain	n (%)	0	2 (8.0)	-		-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_36

DATE: 16JUL2024 5:40

Table Saf_36

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Corneal scar	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Keratopathy	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Punctate keratitis	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Abnormal sensation in eye	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_36

DATE: 16JUL2024 5:40

Table Saf_36

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Lacrimation increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Endophthalmitis	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_36

DATE: 16JUL2024 5:40

Table Saf_36

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
General disorders and administration site conditions							
Injection site pain	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_36

DATE: 16JUL2024 5:40

Table Saf_36

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=6)			p-value[2]	
At Least 1 TEAE Related to Study Medication Administration Procedure	n (%)	3 (20.0)	1 (16.7)	0.8000 (0.0662, 9.6689)	0.8333 (0.1067, 6.5098)	-0.0333 (-0.3937, 0.3271)	0.8638
Eye disorders	n (%)	1 (6.7)	1 (16.7)	2.8000 (0.1460, 53.7064)	2.5000 (0.1847, 33.8316)	0.1000 (-0.2238, 0.4238)	0.4913
Blindness transient	n (%)	0	1 (16.7)	-	-	-	-
Conjunctival haemorrhage	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_36

DATE: 16JUL2024 5:40

Table Saf_36

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=6)			
Investigations	n (%)	1 (6.7)	1 (16.7)	-	-	-
				-	-	-
Intraocular pressure increased	n (%)	1 (6.7)	1 (16.7)	-	-	-
				-	-	-
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-
				-	-	-
Injection site pain	n (%)	1 (6.7)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_36

DATE: 16JUL2024 5:40

Table Saf_36

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by
Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 TEAE Related to Study Medication Administration Procedure	p-value [3]	0.4688
Eye disorders	p-value [3]	0.9292

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_36

DATE: 16JUL2024 5:40

Table Saf_37

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Related to Study Drug	n (%)	3 (20.0)	2 (8.0)	-	-	-	-
Eye disorders	n (%)	3 (20.0)	1 (4.0)	-	-	-	-
Eye pain	n (%)	0	1 (4.0)	-	-	-	-
Abnormal sensation in eye	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_37

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Eye disorders							
Cataract	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Endophthalmitis	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_37

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-	-
Injection site pain	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_37

DATE: 11JUL2024 13:05

Table Saf_37

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=6)			
At Least 1 TEAE Related to Study Drug	n (%)	1 (6.7)	1 (16.7)	- -	- -	- -
Investigations	n (%)	1 (6.7)	1 (16.7)	- -	- -	- -
Intraocular pressure increased	n (%)	1 (6.7)	1 (16.7)	- -	- -	- -
Eye disorders	n (%)	0	1 (16.7)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_37

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value
Eye disorders							
Blindness transient		n (%)	0	1 (16.7)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_37

DATE: 11JUL2024 13:05

Table Saf_38

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	4 (26.7)	8 (32.0)	1.2941 (0.3129, 5.3527)	1.2000 (0.4348, 3.3122)		0.0533 (-0.2357, 0.3423) 0.7249
Eye disorders	n (%)	4 (26.7)	7 (28.0)	1.0694 (0.2535, 4.5110)	1.0500 (0.3680, 2.9961)		0.0133 (-0.2714, 0.2980) 0.9281
Conjunctival haemorrhage	n (%)	1 (6.7)	4 (16.0)	-	-		-
Eye pain	n (%)	0	2 (8.0)	-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_38

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Corneal scar	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Keratopathy	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Punctate keratitis	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Abnormal sensation in eye	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_38

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Cataract	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	1 (6.7)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-
Endophthalmitis	n (%)	0	1 (4.0)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_38

DATE: 16JUL2024 5:40

Table Saf_38

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-	-
Injection site pain	n (%)	1 (6.7)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_38

DATE: 16JUL2024 5:40

Table Saf_38

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	3 (20.0)	1 (16.7)	0.8000 (0.0662, 9.6689)	0.8333 (0.1067, 6.5098)		-0.0333 (-0.3937, 0.3271) 0.8638
Eye disorders	n (%)	1 (6.7)	1 (16.7)	2.8000 (0.1460, 53.7064)	2.5000 (0.1847, 33.8316)		0.1000 (-0.2238, 0.4238) 0.4913
Blindness transient	n (%)	0	1 (16.7)	-	-		-
Conjunctival haemorrhage	n (%)	1 (6.7)	0	-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_38

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=6)			
Investigations	n (%)	1 (6.7)	1 (16.7)	-	-	-
				-	-	-
Intraocular pressure increased	n (%)	1 (6.7)	1 (16.7)	-	-	-
				-	-	-
General disorders and administration site conditions	n (%)	1 (6.7)	0	-	-	-
				-	-	-
Injection site pain	n (%)	1 (6.7)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_38

DATE: 16JUL2024 5:40

Table Saf_38

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	p-value [3]	0.7557
Eye disorders	p-value [3]	0.7302

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.
 [3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
 In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
 Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_38

DATE: 16JUL2024 5:40

Table Saf_39

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=25)			
At Least 1 Serious TEAE Related to Study Drug	n (%)	0	1 (4.0)	-	-	-
				-	-	-
Infections and infestations	n (%)	0	1 (4.0)	-	-	-
				-	-	-
Endophthalmitis	n (%)	0	1 (4.0)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_39

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=6)			
At Least 1 Serious TEAE Related to Study Drug	n (%)	0	1 (16.7)	-	-	-
				-	-	-
Eye disorders	n (%)	0	1 (16.7)	-	-	-
				-	-	-
Blindness transient	n (%)	0	1 (16.7)	-	-	-
				-	-	-
Investigations	n (%)	0	1 (16.7)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_39

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Investigations							
Intraocular pressure increased	n (%)	0	1 (16.7)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_39

DATE: 12JUL2024 8:40

Table Saf_40

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious TEAE Related to Study Medication Administration Procedure	n (%)	0	1 (4.0)	-	-	-	-
Infections and infestations	n (%)	0	1 (4.0)	-	-	-	-
Endophthalmitis	n (%)	0	1 (4.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_40

DATE: 13JUL2024 4:31

Table Saf_40

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious TEAE Related to Study Medication Administration Procedure	n (%)	0	1 (16.7)	-	-	-	-
Eye disorders	n (%)	0	1 (16.7)	-	-	-	-
Blindness transient	n (%)	0	1 (16.7)	-	-	-	-
Investigations	n (%)	0	1 (16.7)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_40

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Investigations							
Intraocular pressure increased	n (%)	0	1 (16.7)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_40

DATE: 13JUL2024 4:31

Table Saf_41

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes						
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
At Least 1 Serious TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	0	1 (4.0)	-	-	-
				-	-	-
Infections and infestations	n (%)	0	1 (4.0)	-	-	-
				-	-	-
Endophthalmitis	n (%)	0	1 (4.0)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_41

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=6)			
At Least 1 Serious TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	0	1 (16.7)	- -	- -	- -
Eye disorders	n (%)	0	1 (16.7)	- -	- -	- -
Blindness transient	n (%)	0	1 (16.7)	- -	- -	- -
Investigations	n (%)	0	1 (16.7)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_41

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Investigations							
Intraocular pressure increased	n (%)	0	1 (16.7)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_41

DATE: 13JUL2024 11:45

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value
At Least 1 TEAE		n (%)	7 (46.7)	20 (80.0)	4.5714 (1.1156, 18.7325)	1.7143 (0.9642, 3.0478)	0.3333 (0.0361, 0.6305)	0.0314
Eye disorders	Grade 1	n (%)	4 (26.7)	9 (36.0)	1.5469 (0.3792, 6.3099)	1.3500 (0.5023, 3.6283)	0.0933 (-0.1990, 0.3857)	0.5469
	Grade 2	n (%)	1 (6.7)	3 (12.0)	-	-	-	-
	Grade 3	n (%)	0	1 (4.0)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	1 (6.7)	4 (16.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eye pain	Grade 1	n (%)	0	2 (8.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Posterior capsule opacification	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	2 (8.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blepharitis	Grade 1	n (%)	1 (6.7)	1 (4.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Corneal scar	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (4.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Dry eye	Grade 1	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Keratopathy	Grade 1	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Lenticular opacities	Grade 1	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Punctate keratitis	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Subretinal fluid	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (4.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Visual impairment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous detachment	Grade 1	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Abnormal sensation in eye	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cataract	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Lacrimation increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Scleromalacia	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	Grade 1	n (%)	0	7 (28.0)	-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	1 (6.7)	4 (16.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood creatinine increased	Grade 1	n (%)	0	2 (8.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Protein urine present	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	1 (6.7)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood albumin increased	Grade 1	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure systolic increased	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea increased	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Platelet morphology abnormal	Grade 1	n (%)	0	1 (4.0)	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

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Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cell rouleaux formation present	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cells urine positive	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Urinary casts	Grade 1	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Infections and infestations	Grade 1	n (%)	0	3 (12.0)	-	-	-	-
	Grade 2	n (%)	0	1 (4.0)	-	-	-	-
	Grade 3	n (%)	0	1 (4.0)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	2 (8.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Candida infection	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Endophthalmitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Influenza	Grade 1	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Kidney infection	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

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Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Tooth infection	Grade 1	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	1 (4.0)	-	-	-	-
	Grade 2	n (%)	0	1 (4.0)	-	-	-	-
	Grade 3	n (%)	1 (6.7)	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 3	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Rheumatoid arthritis	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Blood and lymphatic system disorders	Grade 1	n (%)	0	2 (8.0)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Lymphadenopathy	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Macrocytosis	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders	Grade 1	n (%)	0	2 (8.0)	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Glycosuria	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

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Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Renal tubular acidosis	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	1 (6.7)	1 (4.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Macular scar	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Contusion	Grade 1	n (%)	1 (6.7)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 2	n (%)	1 (6.7)	1 (4.0)	-	-	-	
					-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	0	0	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Basal cell carcinoma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	1 (4.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Gastrointestinal disorders	Grade 1	n (%)	0	1 (4.0)	-	-	-	
					-	-	-	
	Grade 2	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	0	0	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Diarrhoea	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Immune system disorders	Grade 1	n (%)	0	1 (4.0)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Seasonal allergy	Grade 1	n (%)	0	1 (4.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Metabolism and nutrition disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	1 (4.0)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypercholesterolemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Type 2 diabetes mellitus	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	1 (4.0)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Confusional state	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

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Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Vascular disorders	Grade 1	n (%)	0	1 (4.0)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Dizziness	Grade 1	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
General disorders and administration site conditions	Grade 1	n (%)	0	0	-	-	-	
	Grade 2	n (%)	1 (6.7)	0	-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
	Grade 5	n (%)	0	0	-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Skin and subcutaneous tissue disorders	Grade 1	n (%)	1 (6.7)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Brow ptosis	Grade 1	n (%)	1 (6.7)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
At Least 1 TEAE		n (%)	13 (86.7)	5 (83.3)	0.7692 (0.0564, 10.4886)	0.9615 (0.6386, 1.4477)	-0.0333 (-0.3776, 0.3109)	0.8474
Eye disorders	Grade 1	n (%)	3 (20.0)	1 (16.7)	0.8000 (0.0662, 9.6689)	0.8333 (0.1067, 6.5098)	-0.0333 (-0.3937, 0.3271)	0.8638
	Grade 2	n (%)	3 (20.0)	1 (16.7)	-	-	-	-
	Grade 3	n (%)	1 (6.7)	1 (16.7)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	2 (13.3)	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	1 (6.7)	1 (16.7)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

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Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Neovascular age-related macular degeneration	Grade 1	n (%)	1 (6.7)	0	- -	- -	- -
	Grade 2	n (%)	1 (6.7)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blindness transient	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (16.7)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Choroidal neovascularisation	Grade 1	n (%)	0	1 (16.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctivitis allergic	Grade 1	n (%)	0	1 (16.7)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Seasonal allergy	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (16.7)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Diabetic retinal oedema	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Investigations	Grade 1	n (%)	7 (46.7)	1 (16.7)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	1 (16.7)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea increased	Grade 1	n (%)	3 (20.0)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	3 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood triglycerides increased	Grade 1	n (%)	1 (6.7)	1 (16.7)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Eosinophil count increased	Grade 1	n (%)	1 (6.7)	1 (16.7)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (16.7)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Aspartate aminotransferase increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood creatinine increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood glucose increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood lactate dehydrogenase increased	Grade 1	n (%)	1 (6.7)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood sodium increased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Platelet count decreased	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Infections and infestations	Grade 1	n (%)	3 (20.0)	1 (16.7)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Influenza	Grade 1	n (%)	2 (13.3)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	1 (16.7)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Conjunctivitis	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Gastrointestinal disorders	Grade 1	n (%)	2 (13.3)	1 (16.7)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Pancreatitis	Grade 1	n (%)	0	1 (16.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Tooth abscess	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Vomiting	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

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Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	1 (6.7)	0	-	-	-	-
	Grade 2	n (%)	2 (13.3)	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Ankle fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	1 (6.7)	0	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Wrist fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Endocrine disorders	Grade 1	n (%)	0	1 (16.7)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Endocrine disorders							
Hyperthyroidism	Grade 1	n (%)	0	1 (16.7)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
General disorders and administration site conditions	Grade 1	n (%)	1 (6.7)	0	-	-	-	
					-	-	-	
	Grade 2	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	0	0	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
Grade 4	n (%)	0	0		-	-	-
					-	-	-
Grade 5	n (%)	0	0		-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Insomnia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Skin and subcutaneous tissue disorders							
Skin laceration	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Vascular disorders	Grade 1	n (%)	1 (6.7)	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypertension	Grade 1	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Date of data extract: 26AUG2020

Table Saf_42

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic p-value [3]	Interaction p-value [3]
At Least 1 TEAE			0.0373
Eye disorders	Grade 1	p-value [3]	0.6091

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_42

DATE: 16JUL2024 5:41

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class	Maximum MedDRA Preferred CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value	
At Least 1 Serious TEAE		n (%)	1 (6.7)	3 (12.0)	-	-	-	-
Infections and infestations	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	1 (4.0)	-	-	-	-
	Grade 3	n (%)	0	1 (4.0)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations							
Endophthalmitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (4.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders							
Visual impairment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (4.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes								
MedDRA System Organ Class	Maximum MedDRA Preferred CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	1 (6.7)	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Musculoskeletal and connective tissue disorders Back pain							
	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data) [1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE		n (%)	1 (6.7)	1 (16.7)	-	-	-
Eye disorders	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (16.7)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders							
Blindness transient	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (16.7)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (16.7)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations							
Intraocular pressure increased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (16.7)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No								
MedDRA System Organ Class	Maximum MedDRA Preferred CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value	
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_43

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Musculoskeletal and connective tissue disorders Ankle fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (6.7)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
Grade 4	n (%)	0	0	0	-	-	-
					-	-	-
Grade 5	n (%)	0	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_43

DATE: 15JUL2024 6:09

Table Saf_44

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	0	3 (12.0)	-	-	-	-
Eye disorders	n (%)	0	2 (8.0)	-	-	-	-
Subretinal fluid	n (%)	0	1 (4.0)	-	-	-	-
Visual acuity reduced	n (%)	0	1 (4.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_44

DATE: 14JUL2024 7:48

Table Saf_44

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=15)	(Masked Data)[1] (N=25)			
Infections and infestations	n (%)	0	1 (4.0)	-	-	-
Endophthalmitis	n (%)	0	1 (4.0)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_44

DATE: 14JUL2024 7:48

Table Saf_44

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Previous Anti-VEGF Therapy in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=6)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	3 (20.0)	0	-	-	-	-
Eye disorders	n (%)	3 (20.0)	0	-	-	-	-
Visual acuity reduced	n (%)	3 (20.0)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_44

DATE: 14JUL2024 7:48

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
At Least 1 TEAE	n (%)	15 (71.4)	12 (80.0)	1.6000 (0.3295, 7.7693)	1.1200 (0.7733, 1.6221)	0.0857 (-0.1941, 0.3655)	0.5637
Eye disorders	n (%)	11 (52.4)	7 (46.7)	0.7955 (0.2109, 3.0002)	0.8909 (0.4525, 1.7541)	-0.0571 (-0.3879, 0.2736)	0.7389
Visual acuity reduced	n (%)	4 (19.0)	1 (6.7)	-	-	-	-
Conjunctival haemorrhage	n (%)	1 (4.8)	3 (20.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Eye disorders						
Lacrimation increased	n (%)	2 (9.5)	0	-	-	-
				-	-	-
Neovascular age-related macular degeneration	n (%)	2 (9.5)	0	-	-	-
				-	-	-
Blepharitis	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Choroidal neovascularisation	n (%)	0	1 (6.7)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Eye disorders						
Conjunctivitis allergic	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Corneal scar	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Dry eye	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Eye pain	n (%)	0	1 (6.7)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Eye disorders						
Lenticular opacities	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Vitreous detachment	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Abnormal sensation in eye	n (%)	1 (4.8)	0	-	-	-
				-	-	-
Cataract	n (%)	1 (4.8)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders						
Diabetic retinal oedema	n (%)	1 (4.8)	0	-	-	-
				-	-	-
Investigations	n (%)	5 (23.8)	5 (33.3)	1.6000 (0.3679, 6.9586)	1.4000 (0.4911, 3.9913)	0.0952 (-0.2049, 0.3954) 0.5351
White blood cells urine positive	n (%)	1 (4.8)	3 (20.0)	-	-	-
				-	-	-
Blood urea increased	n (%)	2 (9.5)	1 (6.7)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations						
Eosinophil count increased	n (%)	1 (4.8)	1 (6.7)	-	-	-
Blood albumin increased	n (%)	0	1 (6.7)	-	-	-
Blood creatinine increased	n (%)	0	1 (6.7)	-	-	-
Blood pressure systolic increased	n (%)	0	1 (6.7)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) [1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations						
Blood triglycerides increased	n (%)	0	1 (6.7)	- -	- -	- -
Red blood cells urine positive	n (%)	0	1 (6.7)	- -	- -	- -
Aspartate aminotransferase increased	n (%)	1 (4.8)	0	- -	- -	- -
Blood glucose increased	n (%)	1 (4.8)	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations						
Blood lactate dehydrogenase increased	n (%)	1 (4.8)	0	-	-	-
Blood sodium increased	n (%)	1 (4.8)	0	-	-	-
Intraocular pressure increased	n (%)	1 (4.8)	0	-	-	-
Platelet count decreased	n (%)	1 (4.8)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Infections and infestations	n (%)	3 (14.3)	2 (13.3)	-	-	-
Influenza	n (%)	2 (9.5)	1 (6.7)	-	-	-
Endophthalmitis	n (%)	0	1 (6.7)	-	-	-
Conjunctivitis	n (%)	1 (4.8)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations						
Lower respiratory tract infection	n (%)	1 (4.8)	0	- -	- -	- -
Musculoskeletal and connective tissue disorders	n (%)	4 (19.0)	1 (6.7)	- -	- -	- -
Back pain	n (%)	2 (9.5)	1 (6.7)	- -	- -	- -
Ankle fracture	n (%)	1 (4.8)	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) [1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value [2]
Musculoskeletal and connective tissue disorders						
Wrist fracture	n (%)	1 (4.8)	0	- -	- -	- -
Gastrointestinal disorders	n (%)	1 (4.8)	1 (6.7)	- -	- -	- -
Pancreatitis	n (%)	0	1 (6.7)	- -	- -	- -
Vomiting	n (%)	1 (4.8)	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Psychiatric disorders	n (%)	1 (4.8)	1 (6.7)	-	-	-
				-	-	-
Confusional state	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Insomnia	n (%)	1 (4.8)	0	-	-	-
				-	-	-
General disorders and administration site conditions	n (%)	2 (9.5)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions						
Injection site pain	n (%)	2 (9.5)	0	- -	- -	- -
Immune system disorders	n (%)	0	1 (6.7)	- -	- -	- -
Seasonal allergy	n (%)	0	1 (6.7)	- -	- -	- -
Metabolism and nutrition disorders	n (%)	0	1 (6.7)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Metabolism and nutrition disorders						
Hypercholesterolaemia	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Type 2 diabetes mellitus	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Injury, poisoning and procedural complications	n (%)	1 (4.8)	0	-	-	-
				-	-	-
Contusion	n (%)	1 (4.8)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Skin and subcutaneous tissue disorders	n (%)	1 (4.8)	0	-	-	-
				-	-	-
Skin laceration	n (%)	1 (4.8)	0	-	-	-
				-	-	-

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE	n (%)	5 (55.6)	13 (81.3)	3.4667 (0.5629, 21.3502)	1.4625 (0.7789, 2.7459)	0.2569 (-0.1198, 0.6337) 0.1784
Eye disorders	n (%)	1 (11.1)	9 (56.3)	10.2857 (1.0296, 102.7534)	5.0625 (0.7589, 33.7705)	0.4514 (0.1332, 0.7696) 0.0303
Conjunctival haemorrhage	n (%)	1 (11.1)	2 (12.5)	-	-	-
Posterior capsule opacification	n (%)	0	2 (12.5)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Eye disorders						
Blindness transient	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Eye pain	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Keratopathy	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Punctate keratitis	n (%)	0	1 (6.3)	-	-	-
				-	-	-

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Eye disorders						
Seasonal allergy	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Subretinal fluid	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Visual impairment	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Blepharitis	n (%)	1 (11.1)	0	-	-	-
				-	-	-

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters						
MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders						
Scleromalacia	n (%)	1 (11.1)	0	-	-	-
				-	-	-
Investigations	n (%)	3 (33.3)	4 (25.0)	0.6667 (0.1114, 3.9898)	0.7500 (0.2139, 2.6297)	-0.0833 (-0.4573, 0.2907) 0.6625
White blood cells urine positive	n (%)	3 (33.3)	1 (6.3)	-	-	-
				-	-	-
Blood creatinine increased	n (%)	1 (11.1)	1 (6.3)	-	-	-
				-	-	-

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[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Protein urine present	n (%)	1 (11.1)	1 (6.3)	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Platelet morphology abnormal	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Red blood cell rouleaux formation present	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations						
Urinary casts	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Blood triglycerides increased	n (%)	1 (11.1)	0	-	-	-
				-	-	-
Blood urea increased	n (%)	1 (11.1)	0	-	-	-
				-	-	-
Infections and infestations	n (%)	0	4 (25.0)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value[2]
MedDRA Preferred Term							
Infections and infestations							
Urinary tract infection	n (%)	0	3 (18.8)	-	-	-	-
				-	-	-	-
Candida infection	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Kidney infection	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Lower respiratory tract infection	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Infections and infestations						
Tooth infection	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Blood and lymphatic system disorders	n (%)	0	2 (12.5)	-	-	-
				-	-	-
Lymphadenopathy	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Macrocytosis	n (%)	0	1 (6.3)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders	n (%)	0	2 (12.5)	-	-	-
Glycosuria	n (%)	0	1 (6.3)	-	-	-
Renal tubular acidosis	n (%)	0	1 (6.3)	-	-	-
Gastrointestinal disorders	n (%)	1 (11.1)	1 (6.3)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders						
Diarrhoea	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Tooth abscess	n (%)	1 (11.1)	0	-	-	-
				-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	1 (11.1)	1 (6.3)	-	-	-
				-	-	-
Basal cell carcinoma	n (%)	1 (11.1)	1 (6.3)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders	n (%)	1 (11.1)	1 (6.3)	-	-	-
				-	-	-
Dizziness	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Hypertension	n (%)	1 (11.1)	0	-	-	-
				-	-	-
Endocrine disorders	n (%)	0	1 (6.3)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) [1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Endocrine disorders						
Hyperthyroidism	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Injury, poisoning and procedural complications	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Macular scar	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Musculoskeletal and connective tissue disorders	n (%)	0	1 (6.3)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

>=68 letters						
MedDRA System Organ Class		Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic					
Musculoskeletal and connective tissue disorders						
Rheumatoid arthritis	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Skin and subcutaneous tissue disorders	n (%)	1 (11.1)	0	-	-	-
				-	-	-
Brow ptosis	n (%)	1 (11.1)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_45

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 TEAE	p-value [3]	0.6748
Eye disorders	p-value [3]	0.1160
Investigations	p-value [3]	0.4448

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_45

DATE: 16JUL2024 5:41

Table Saf_46

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters						
MedDRA System Organ Class		Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic					
At Least 1 Serious TEAE	n (%)	2 (9.5)	1 (6.7)	-	-	-
				-	-	-
Musculoskeletal and connective tissue disorders	n (%)	2 (9.5)	0	-	-	-
Ankle fracture	n (%)	1 (4.8)	0	-	-	-
				-	-	-
Back pain	n (%)	1 (4.8)	0	-	-	-
				-	-	-
Infections and infestations	n (%)	0	1 (6.7)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_46

DATE: 10JUL2024 9:56

Table Saf_46

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Infections and infestations						
Endophthalmitis	n (%)	0	1 (6.7)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_46

DATE: 10JUL2024 9:56

Table Saf_46

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) [1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE	n (%)	0	3 (18.8)	-	-	-
Eye disorders	n (%)	0	2 (12.5)	-	-	-
Blindness transient	n (%)	0	1 (6.3)	-	-	-
Visual impairment	n (%)	0	1 (6.3)	-	-	-
Infections and infestations	n (%)	0	1 (6.3)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_46

DATE: 10JUL2024 9:56

Table Saf_46

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Infections and infestations							
Lower respiratory tract infection	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Investigations	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_46

DATE: 10JUL2024 9:56

Table Saf_47

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=21)	(Masked Data)[1] (N=15)			
At Least 1 TEAE Related to Study Medication Administration Procedure	n (%)	5 (23.8)	4 (26.7)	-	-	-
Eye disorders	n (%)	3 (14.3)	3 (20.0)	-	-	-
Conjunctival haemorrhage	n (%)	1 (4.8)	2 (13.3)	-	-	-
Corneal scar	n (%)	0	1 (6.7)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_47

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by
Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Eye disorders						
Eye pain	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Abnormal sensation in eye	n (%)	1 (4.8)	0	-	-	-
				-	-	-
Lacrimation increased	n (%)	1 (4.8)	0	-	-	-
				-	-	-
General disorders and administration site conditions	n (%)	2 (9.5)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_47

DATE: 11JUL2024 9:49

Table Saf_47

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							Absolute Risk Difference
MedDRA System Organ Class		Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
MedDRA Preferred Term	Statistic						
General disorders and administration site conditions							
Injection site pain	n (%)	2 (9.5)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (6.7)	-	-	-	-
				-	-	-	-
Endophthalmitis	n (%)	0	1 (6.7)	-	-	-	-
				-	-	-	-
Investigations	n (%)	1 (4.8)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_47

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by
Baseline BCVA Value in NORSE-1 Study
(Safety Population)

<=67 letters

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=21)	(Masked Data)[1] (N=15)	Odds Ratio	Relative Risk	Difference
				95% CI	95% CI	95% CI
						p-value
Investigations						
Intraocular pressure increased	n (%)	1 (4.8)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_47

DATE: 11JUL2024 9:49

Table Saf_47

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=9)	(Masked Data)[1] (N=16)			
At Least 1 TEAE Related to Study Medication Administration Procedure	n (%)	1 (11.1)	5 (31.3)	-	-	-
Eye disorders	n (%)	1 (11.1)	5 (31.3)	-	-	-
Conjunctival haemorrhage	n (%)	1 (11.1)	2 (12.5)	-	-	-
Blindness transient	n (%)	0	1 (6.3)	-	-	-
Eye pain	n (%)	0	1 (6.3)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_47

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Eye disorders							
Keratopathy	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Punctate keratitis	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Investigations	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_47

DATE: 11JUL2024 9:49

Table Saf_48

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Related to Study Drug	n (%)	4 (19.0)	2 (13.3)	-	-	-	-
				-	-	-	-
Eye disorders	n (%)	3 (14.3)	1 (6.7)	-	-	-	-
				-	-	-	-
Eye pain	n (%)	0	1 (6.7)	-	-	-	-
				-	-	-	-
Abnormal sensation in eye	n (%)	1 (4.8)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_48

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Eye disorders							
Cataract	n (%)	1 (4.8)	0	-	-	-	-
				-	-	-	-
Lacrimation increased	n (%)	1 (4.8)	0	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (6.7)	-	-	-	-
				-	-	-	-
Endophthalmitis	n (%)	0	1 (6.7)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_48

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
General disorders and administration site conditions	n (%)	1 (4.8)	0	-	-	-	-
Injection site pain	n (%)	1 (4.8)	0	-	-	-	-
Investigations	n (%)	1 (4.8)	0	-	-	-	-
Intraocular pressure increased	n (%)	1 (4.8)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_48

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Related to Study Drug	n (%)	0	1 (6.3)	-	-	-	-
Eye disorders	n (%)	0	1 (6.3)	-	-	-	-
Blindness transient	n (%)	0	1 (6.3)	-	-	-	-
Investigations	n (%)	0	1 (6.3)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_48

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Investigations							
Intraocular pressure increased	n (%)	0	1 (6.3)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_49

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic	Ranibizumab (N=21)	(Masked Data)[1] (N=15)			
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	6 (28.6)	4 (26.7)	0.9091 (0.2059, 4.0146)	0.9333 (0.3177, 2.7422)	-0.0190 (-0.3147, 0.2766) 0.9013
Eye disorders	n (%)	4 (19.0)	3 (20.0)	-	-	-
Conjunctival haemorrhage	n (%)	1 (4.8)	2 (13.3)	-	-	-
Corneal scar	n (%)	0	1 (6.7)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_49

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders						
Eye pain	n (%)	0	1 (6.7)	- -	- -	- -
Abnormal sensation in eye	n (%)	1 (4.8)	0	- -	- -	- -
Cataract	n (%)	1 (4.8)	0	- -	- -	- -
Lacrimation increased	n (%)	1 (4.8)	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_49

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Statistic	Ranibizumab (N=21)	(Masked Data)[1] (N=15)			
General disorders and administration site conditions	n (%)	2 (9.5)	0	- -	- -	- -
Injection site pain	n (%)	2 (9.5)	0	- -	- -	- -
Infections and infestations	n (%)	0	1 (6.7)	- -	- -	- -
Endophthalmitis	n (%)	0	1 (6.7)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_49

DATE: 16JUL2024 5:42

Table Saf_49

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	n (%)	1 (4.8)	0	-	-	-
				-	-	-
Intraocular pressure increased	n (%)	1 (4.8)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_49

DATE: 16JUL2024 5:42

Table Saf_49

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	1 (11.1)	5 (31.3)	3.6364 (0.3530, 37.4566)	2.8125 (0.3861, 20.4858)		0.2014 (-0.1048, 0.5076) 0.2675
Eye disorders	n (%)	1 (11.1)	5 (31.3)	-	-	-	-
Conjunctival haemorrhage	n (%)	1 (11.1)	2 (12.5)	-	-	-	-
Blindness transient	n (%)	0	1 (6.3)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_49

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) [1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term						
Eye disorders						
Eye pain	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Keratopathy	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Punctate keratitis	n (%)	0	1 (6.3)	-	-	-
				-	-	-
Investigations	n (%)	0	1 (6.3)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_49

DATE: 16JUL2024 5:42

Table Saf_49

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Intraocular pressure increased	n (%)	0	1 (6.3)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_49

DATE: 16JUL2024 5:42

Table Saf_49

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in
NORSE-1 Study
(Safety Population)

MedDRA System Organ Class

MedDRA Preferred Term

At Least 1 TEAE Related to Either Study Drug or Study Medication Administration
Procedure

Statistic

p-value [3]

Interaction

0.4425

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to either study drug or study medication administration procedure per investigator.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_49

DATE: 16JUL2024 5:42

Table Saf_50

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
At Least 1 Serious TEAE Related to Study Drug	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Infections and infestations	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Endophthalmitis	n (%)	0	1 (6.7)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_50

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters						
MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE Related to Study Drug	n (%)	0	1 (6.3)	- -	- -	- -
Eye disorders	n (%)	0	1 (6.3)	- -	- -	- -
Blindness transient	n (%)	0	1 (6.3)	- -	- -	- -
Investigations	n (%)	0	1 (6.3)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_50

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) [1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Investigations							
Intraocular pressure increased	n (%)	0	1 (6.3)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_51

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value
At Least 1 Serious TEAE Related to Study Medication Administration Procedure	n (%)	0	1 (6.7)	-	-	-	-
Infections and infestations	n (%)	0	1 (6.7)	-	-	-	-
Endophthalmitis	n (%)	0	1 (6.7)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_51

DATE: 13JUL2024 5:07

Table Saf_51

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
At Least 1 Serious TEAE Related to Study Medication Administration Procedure	n (%)	0	1 (6.3)	-	-	-
Eye disorders	n (%)	0	1 (6.3)	-	-	-
Blindness transient	n (%)	0	1 (6.3)	-	-	-
Investigations	n (%)	0	1 (6.3)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_51

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Investigations							
Intraocular pressure increased	n (%)	0	1 (6.3)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_51

DATE: 13JUL2024 5:07

Table Saf_52

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
At Least 1 Serious TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Infections and infestations	n (%)	0	1 (6.7)	-	-	-
				-	-	-
Endophthalmitis	n (%)	0	1 (6.7)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_52

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Eye disorders	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Blindness transient	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Investigations	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_52

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) [1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Investigations						
Intraocular pressure increased	n (%)	0	1 (6.3)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_52

DATE: 13JUL2024 12:04

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
At Least 1 TEAE		n (%)	15 (71.4)	12 (80.0)	1.6000 (0.3295, 7.7693)	1.1200 (0.7733, 1.6221)	0.0857 (-0.1941, 0.3655)	0.5637
Eye disorders	Grade 1	n (%)	6 (28.6)	6 (40.0)	1.6667 (0.4105, 6.7669)	1.4000 (0.5594, 3.5036)	0.1143 (-0.2000, 0.4286)	0.4795
	Grade 2	n (%)	4 (19.0)	1 (6.7)	-	-	-	-
	Grade 3	n (%)	1 (4.8)	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	3 (14.3)	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	1 (4.8)	3 (20.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	2 (9.5)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Neovascular age-related macular degeneration	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
					-	-	-
	Grade 2	n (%)	1 (4.8)	0	-	-	-
					-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

<=67 letters

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Blepharitis	Grade 1	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

<=67 letters

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Eye disorders							
Choroidal neovascularisation	Grade 1	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctivitis allergic	Grade 1	n (%)	0	1 (6.7)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Corneal scar	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Dry eye	Grade 1	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eye pain	Grade 1	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lenticular opacities	Grade 1	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous detachment	Grade 1	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Abnormal sensation in eye	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cataract	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Diabetic retinal oedema	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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<=67 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	Grade 1	n (%)	5 (23.8)	5 (33.3)	1.6000 (0.3679, 6.9586)	1.4000 (0.4911, 3.9913)	0.0952 (-0.2049, 0.3954) 0.5351
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

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<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	1 (4.8)	3 (20.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea increased	Grade 1	n (%)	2 (9.5)	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Eosinophil count increased	Grade 1	n (%)	1 (4.8)	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Investigations							
Blood albumin increased	Grade 1	n (%)	0	1 (6.7)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	0	1 (6.7)	-	-	-
creatinine					-	-	-
increased	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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<=67 letters

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure systolic increased	Grade 1	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood	Grade 1	n (%)	0	1 (6.7)	-	-	-
triglycerides					-	-	-
increased	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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<=67 letters

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cells urine positive	Grade 1	n (%)	0	1 (6.7)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Aspartate aminotransferase increased	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood glucose increased	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood lactate dehydrogenase increased	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood sodium increased	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Platelet count decreased	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations	Grade 1	n (%)	3 (14.3)	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Influenza	Grade 1	n (%)	2 (9.5)	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Endophthalmitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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<=67 letters

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Conjunctivitis	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	1 (4.8)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	2 (9.5)	1 (6.7)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (4.8)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	1 (4.8)	0	- -	- -	- -
	Grade 2	n (%)	0	1 (6.7)	- -	- -	- -
	Grade 3	n (%)	1 (4.8)	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Ankle fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Wrist fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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<=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Gastrointestinal disorders	Grade 1	n (%)	1 (4.8)	1 (6.7)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Pancreatitis	Grade 1	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Vomiting	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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<=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (4.8)	1 (6.7)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Confusional state	Grade 1	n (%)	0	0	- -	- -	- -
	Grade 2	n (%)	0	1 (6.7)	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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<=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Insomnia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters

MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions	Grade 1	n (%)	1 (4.8)	0	-	-	-
	Grade 2	n (%)	1 (4.8)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain	Grade 1	n (%)	1 (4.8)	0	- -	- -	- -
	Grade 2	n (%)	1 (4.8)	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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<=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Immune system disorders	Grade 1	n (%)	0	1 (6.7)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Seasonal allergy	Grade 1	n (%)	0	1 (6.7)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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<=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Metabolism and nutrition disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	1 (6.7)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypercholesterolemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Type 2 diabetes mellitus	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	1 (4.8)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Contusion	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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<=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	1 (4.8)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Skin laceration	Grade 1	n (%)	1 (4.8)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
At Least 1 TEAE		n (%)	5 (55.6)	13 (81.3)	3.4667 (0.5629,21.3502)	1.4625 (0.7789, 2.7459)	0.2569 (-0.1198,0.6337) 0.1784	
Eye disorders	Grade 1	n (%)	1 (11.1)	4 (25.0)	2.6667 (0.2501,28.4376)	2.2500 (0.2945,17.1908)	0.1389 (-0.1564,0.4341) 0.4142	
	Grade 2	n (%)	0	3 (18.8)	-	-	-	
	Grade 3	n (%)	0	2 (12.5)	-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
	Grade 5	n (%)	0	0	-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	1 (11.1)	2 (12.5)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders Posterior capsule opacification	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	2 (12.5)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blindness transient	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eye pain	Grade 1	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Keratopathy	Grade 1	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Punctate keratitis	Grade 1	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Seasonal allergy	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (6.3)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Subretinal fluid	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (6.3)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Visual impairment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blepharitis	Grade 1	n (%)	1 (11.1)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Scleromalacia	Grade 1	n (%)	1 (11.1)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	Grade 1	n (%)	2 (22.2)	3 (18.8)	0.8077 (0.1081, 6.0362)	0.8438 (0.1717, 4.1456)	-0.0347 (-0.3669, 0.2975) 0.8383
	Grade 2	n (%)	1 (11.1)	0	-	-	-
	Grade 3	n (%)	0	1 (6.3)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	3 (33.3)	1 (6.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood creatinine increased	Grade 1	n (%)	1 (11.1)	1 (6.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Protein urine present	Grade 1	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (11.1)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations Intraocular pressure increased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Platelet	Grade 1	n (%)	0	1 (6.3)	-	-	-
morphology					-	-	-
abnormal	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>=68 letters

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cell rouleaux formation present	Grade 1	n (%)	0	1 (6.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Urinary casts	Grade 1	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>=68 letters							
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Investigations							
Blood	Grade 1	n (%)	1 (11.1)	0	-	-	-
triglycerides							
increased	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

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MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea increased	Grade 1	n (%)	1 (11.1)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Infections and infestations	Grade 1	n (%)	0	3 (18.8)	-	-	-	-
	Grade 2	n (%)	0	1 (6.3)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	3 (18.8)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Candida infection	Grade 1	n (%)	0	1 (6.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Kidney infection	Grade 1	n (%)	0	1 (6.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Tooth infection	Grade 1	n (%)	0	1 (6.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Blood and lymphatic system disorders	Grade 1	n (%)	0	2 (12.5)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

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>=68 letters							
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Blood and lymphatic system disorders							
Lymphadenopathy	Grade 1	n (%)	0	1 (6.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 5:42

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Macrocytosis	Grade 1	n (%)	0	1 (6.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Renal and urinary disorders	Grade 1	n (%)	0	2 (12.5)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Glycosuria	Grade 1	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Renal tubular acidosis	Grade 1	n (%)	0	1 (6.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Gastrointestinal disorders	Grade 1	n (%)	1 (11.1)	1 (6.3)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Diarrhoea	Grade 1	n (%)	0	1 (6.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Tooth abscess	Grade 1	n (%)	1 (11.1)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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>=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (11.1)	1 (6.3)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 5:42

>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Basal cell carcinoma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (11.1)	1 (6.3)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
MedDRA Preferred Term	Grade	n (%)						
Vascular disorders	Grade 1	n (%)	1 (11.1)	1 (6.3)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Dizziness	Grade 1	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypertension	Grade 1	n (%)	1 (11.1)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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>=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Endocrine disorders	Grade 1	n (%)	0	1 (6.3)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Endocrine disorders							
Hyperthyroidism	Grade 1	n (%)	0	1 (6.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

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Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	0	1 (6.3)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Macular scar	Grade 1	n (%)	0	1 (6.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	1 (6.3)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Rheumatoid arthritis	Grade 1	n (%)	0	1 (6.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	1 (11.1)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders Brow ptosis	Grade 1	n (%)	1 (11.1)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 5:42

Date of data extract: 26AUG2020

Table Saf_53

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic p-value [3]	Interaction
At Least 1 TEAE			0.6748
Eye disorders	Grade 1	p-value [3]	0.8555
Investigations	Grade 1	p-value [3]	0.5051

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.
[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_53

DATE: 16JUL2024 5:42

Table Saf_54

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters								Absolute Risk Difference
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value
At Least 1 Serious TEAE		n (%)	2 (9.5)	1 (6.7)	-	-	-	-
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (4.8)	0	-	-	-	-
	Grade 3	n (%)	1 (4.8)	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_54

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters								Absolute Risk Difference
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data) [1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Musculoskeletal and connective tissue disorders	Ankle fracture	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (4.8)	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_54

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters								Absolute Risk Difference
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Musculoskeletal and connective tissue disorders Back pain								
	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (4.8)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_54

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_54

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations	Endophthalmitis Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (6.7)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_54

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE		n (%)	0	3 (18.8)	-	-	-
Eye disorders	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	2 (12.5)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_54

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders							
Blindness transient	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_54

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders							
Visual impairment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_54

DATE: 15JUL2024 6:51

Table Saf_54

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_54

DATE: 15JUL2024 6:51

Table Saf_54

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations Lower respiratory tract infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_54

DATE: 15JUL2024 6:51

Table Saf_54

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_54

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data)[1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations							
Intraocular pressure increased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (6.3)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_54

DATE: 15JUL2024 6:51

Table Saf_55

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=21)	(Masked Data)[1] (N=15)			
At Least 1 TEAE Leading to Study Withdrawal	n (%)	3 (14.3)	2 (13.3)	- -	- -	- -
Eye disorders	n (%)	3 (14.3)	1 (6.7)	- -	- -	- -
Visual acuity reduced	n (%)	3 (14.3)	1 (6.7)	- -	- -	- -
Infections and infestations	n (%)	0	1 (6.7)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_55

DATE: 14JUL2024 9:01

Table Saf_55

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

<=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=21)	ONS-5010 (Masked Data)[1] (N=15)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Infections and infestations							
Endophthalmitis	n (%)	0	1 (6.7)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_55

DATE: 14JUL2024 9:01

Table Saf_55

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value in NORSE-1 Study (Safety Population)

>=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=9)	ONS-5010 (Masked Data) [1] (N=16)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Eye disorders	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-
Subretinal fluid	n (%)	0	1 (6.3)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_55

DATE: 14JUL2024 9:01

Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data) (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE		n (%)	5 (45.5)	9 (81.8)	5.4000 (0.7775, 37.5046)	1.8000 (0.8896, 3.6420)	0.3636 (-0.0086,0.7358) 0.0833
Eye disorders		n (%)	4 (36.4)	6 (54.5)	2.1000 (0.3805, 11.5890)	1.5000 (0.5802, 3.8779)	0.1818 (-0.2273,0.5910) 0.4028
Conjunctival haemorrhage		n (%)	0	2 (18.2)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_56

DATE: 16JUL2024 5:43

Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data) (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Visual acuity reduced	n (%)	1 (9.1)	1 (9.1)	-	-	-	-
							-
Blepharitis	n (%)	0	1 (9.1)	-	-	-	-
							-
Corneal scar	n (%)	0	1 (9.1)	-	-	-	-
							-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_56

DATE: 16JUL2024 5:43

Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data) (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Dry eye		n (%)	0	1 (9.1)	-	-	-
					-	-	-
Eye pain		n (%)	0	1 (9.1)	-	-	-
					-	-	-
Lenticular opacities		n (%)	0	1 (9.1)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_56

DATE: 16JUL2024 5:43

Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data) (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Vitreous detachment		n (%)	0	1 (9.1)	-	-	-
					-	-	-
Abnormal sensation in eye		n (%)	1 (9.1)	0	-	-	-
					-	-	-
Cataract		n (%)	1 (9.1)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_56

DATE: 16JUL2024 5:43

Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data) (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Eye disorders							
Lacrimation increased	n (%)	1 (9.1)	0	-	-	-	-
Investigations	n (%)	0	4 (36.4)	-	-	-	-
White blood cells urine positive	n (%)	0	3 (27.3)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_56

DATE: 16JUL2024 5:43

Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
 (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data) (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Investigations							
Blood albumin increased	n (%)	0	1 (9.1)	-	-	-	-
Blood creatinine increased	n (%)	0	1 (9.1)	-	-	-	-
Blood pressure systolic increased	n (%)	0	1 (9.1)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_56

DATE: 16JUL2024 5:43

Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data) (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Investigations							
Blood urea increased	n (%)	0	1 (9.1)	-	-	-	-
							-
Red blood cells urine positive	n (%)	0	1 (9.1)	-	-	-	-
							-
Infections and infestations	n (%)	0	2 (18.2)	-	-	-	-
							-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_56

DATE: 16JUL2024 5:43

Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data) (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Infections and infestations	Endophthalmitis	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Influenza	n (%)	0	1 (9.1)	-	-	-
Musculoskeletal and connective tissue disorders		n (%)	1 (9.1)	1 (9.1)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_56

DATE: 16JUL2024 5:43

Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data) (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Musculoskeletal and connective tissue disorders	Back pain	n (%)	1 (9.1)	1 (9.1)	-	-	-
					-	-	-
					-	-	-
Immune system disorders		n (%)	0	1 (9.1)	-	-	-
					-	-	-
Seasonal allergy		n (%)	0	1 (9.1)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_56

DATE: 16JUL2024 5:43

Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data) (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Metabolism and nutrition disorders		n (%)	0	1 (9.1)	-	-	-
	Hypercholesterolaemia	n (%)	0	1 (9.1)	-	-	-
	Type 2 diabetes mellitus	n (%)	0	1 (9.1)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

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Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data) (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Psychiatric disorders		n (%)	0	1 (9.1)	-	-	-
					-	-	-
Confusional state		n (%)	0	1 (9.1)	-	-	-
					-	-	-
General disorders and administration site conditions		n (%)	1 (9.1)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data) (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
General disorders and administration site conditions	Injection site pain	n (%)	1 (9.1)	0	-	-	-
					-	-	-
Injury, poisoning and procedural complications	Contusion	n (%)	1 (9.1)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE		n (%)	2 (50.0)	11 (78.6)	3.6667 (0.3535, 38.0285)	1.5714 (0.5681, 4.3468)	0.2857 (-0.2493,0.8208) 0.2742
Eye disorders		n (%)	1 (25.0)	7 (50.0)	3.0000 (0.2478, 36.3250)	2.0000 (0.3385, 11.8167)	0.2500 (-0.2487,0.7487) 0.3885
Conjunctival haemorrhage		n (%)	1 (25.0)	2 (14.3)	-	-	-
Posterior capsule opacification		n (%)	0	2 (14.3)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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(Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Eye pain		n (%)	0	1 (7.1)	-	-	-
					-	-	-
Keratopathy		n (%)	0	1 (7.1)	-	-	-
					-	-	-
Punctate keratitis		n (%)	0	1 (7.1)	-	-	-
					-	-	-
Subretinal fluid		n (%)	0	1 (7.1)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Visual impairment	n (%)	0	1 (7.1)	-	-	-	-
Blepharitis	n (%)	1 (25.0)	0	-	-	-	-
Scleromalacia	n (%)	1 (25.0)	0	-	-	-	-
Investigations	n (%)	1 (25.0)	3 (21.4)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Protein urine present	n (%)	1 (25.0)	1 (7.1)	-	-	-	-
				-	-	-	-
White blood cells urine positive	n (%)	1 (25.0)	1 (7.1)	-	-	-	-
				-	-	-	-
Blood creatinine increased	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Platelet morphology abnormal	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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(Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Investigations							
Red blood cell rouleaux formation present		n (%)	0	1 (7.1)	-	-	-
Urinary casts		n (%)	0	1 (7.1)	-	-	-
Infections and infestations		n (%)	0	3 (21.4)	-	-	-
Urinary tract infection		n (%)	0	2 (14.3)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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(Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Infections and infestations							
Candida infection	n (%)	0	1 (7.1)	-	-	-	-
							-
Kidney infection	n (%)	0	1 (7.1)	-	-	-	-
							-
Lower respiratory tract infection	n (%)	0	1 (7.1)	-	-	-	-
							-
Tooth infection	n (%)	0	1 (7.1)	-	-	-	-
							-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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(Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Blood and lymphatic system disorders		n (%)	0	2 (14.3)	-	-	-
	Lymphadenopathy	n (%)	0	1 (7.1)	-	-	-
	Macrocytosis	n (%)	0	1 (7.1)	-	-	-
Renal and urinary disorders		n (%)	0	2 (14.3)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
MedDRA Preferred Term							
Renal and urinary disorders							
Glycosuria	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Renal tubular acidosis	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%)	1 (25.0)	1 (7.1)	-	-	-	-
				-	-	-	-
Basal cell carcinoma	n (%)	1 (25.0)	1 (7.1)	-	-	-	-
				-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Gastrointestinal disorders		n (%)	0	1 (7.1)	-	-	-
Diarrhoea		n (%)	0	1 (7.1)	-	-	-
Injury, poisoning and procedural complications		n (%)	0	1 (7.1)	-	-	-
Macular scar		n (%)	0	1 (7.1)	-	-	-

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(Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Musculoskeletal and connective tissue disorders		n (%)	0	1 (7.1)	-	-	-
	Rheumatoid arthritis	n (%)	0	1 (7.1)	-	-	-
Vascular disorders		n (%)	0	1 (7.1)	-	-	-
	Dizziness	n (%)	0	1 (7.1)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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(Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Skin and subcutaneous tissue disorders		n (%)	1 (25.0)	0	-	-	-
					-	-	-
Brow ptosis		n (%)	1 (25.0)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE		n (%)	10 (100.0)	3 (75.0)	NE (NE, NE)	0.7500 (0.4259, 1.3206)	-0.2500 (-0.6743, 0.1743) 0.1138
Eye disorders		n (%)	7 (70.0)	1 (25.0)	0.1429 (0.0102, 1.9949)	0.3571 (0.0624, 2.0454)	-0.4500 (-0.9606, 0.0606) 0.1386
Visual acuity reduced		n (%)	3 (30.0)	0	-	-	-

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(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage		n (%)	1 (10.0)	1 (25.0)	-	-	-
Neovascular age-related macular degeneration		n (%)	2 (20.0)	0	-	-	-
Choroidal neovascularisation		n (%)	0	1 (25.0)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_56

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Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Eye disorders							
Conjunctivitis allergic		n (%)	0	1 (25.0)	-	-	-
					-	-	-
Diabetic retinal oedema		n (%)	1 (10.0)	0	-	-	-
					-	-	-
Lacrimation increased		n (%)	1 (10.0)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	n (%)	5 (50.0)	1 (25.0)	-	-	-
Eosinophil count increased	n (%)	1 (10.0)	1 (25.0)	-	-	-
Blood urea increased	n (%)	2 (20.0)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Blood triglycerides increased	n (%)	0	1 (25.0)	-	-	-	-
Aspartate aminotransferase increased	n (%)	1 (10.0)	0	-	-	-	-
Blood glucose increased	n (%)	1 (10.0)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Investigations							
Blood lactate dehydrogenase increased	n (%)	1 (10.0)	0	-	-	-	-
Blood sodium increased	n (%)	1 (10.0)	0	-	-	-	-
Intraocular pressure increased	n (%)	1 (10.0)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Investigations							
Platelet count decreased	n (%)	1 (10.0)	0	-	-		-
				-	-		-
White blood cells urine positive	n (%)	1 (10.0)	0	-	-		-
				-	-		-
Infections and infestations	n (%)	3 (30.0)	0	-	-		-
				-	-		-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Infections and infestations							
Influenza		n (%)	2 (20.0)	0	-	-	-
					-	-	-
Conjunctivitis		n (%)	1 (10.0)	0	-	-	-
					-	-	-
Lower respiratory tract infection		n (%)	1 (10.0)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	n (%)	3 (30.0)	0	-	-	-	-
Ankle fracture	n (%)	1 (10.0)	0	-	-	-	-
Back pain	n (%)	1 (10.0)	0	-	-	-	-

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Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Wrist fracture	n (%)	1 (10.0)	0	-	-		-
				-	-		-
Gastrointestinal disorders	n (%)	1 (10.0)	1 (25.0)	-	-		-
				-	-		-
Pancreatitis	n (%)	0	1 (25.0)	-	-		-
				-	-		-

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Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Gastrointestinal disorders							
Vomiting		n (%)	1 (10.0)	0	-	-	-
					-	-	-
General disorders and administration site conditions		n (%)	1 (10.0)	0	-	-	-
					-	-	-
Injection site pain		n (%)	1 (10.0)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders	n (%)	1 (10.0)	0	-	-	-
Insomnia	n (%)	1 (10.0)	0	-	-	-
Skin and subcutaneous tissue disorders	n (%)	1 (10.0)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Skin laceration	n (%)	1 (10.0)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI
MedDRA Preferred Term							p-value[2]
At Least 1 TEAE	n (%)	3 (60.0)	2 (100.0)	NE (NE, NE)	1.6667 (0.8148, 3.4093)		0.4000 (-0.0294, 0.8294) 0.3272
Investigations	n (%)	2 (40.0)	1 (50.0)	-	-	-	-
White blood cells urine positive	n (%)	2 (40.0)	0	-	-	-	-
Intraocular pressure increased	n (%)	0	1 (50.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Investigations							
Blood creatinine increased	n (%)	1 (20.0)	0		-	-	-
							-
							-
Blood triglycerides increased	n (%)	1 (20.0)	0		-	-	-
							-
Blood urea increased	n (%)	1 (20.0)	0		-	-	-
							-
Eye disorders	n (%)	0	2 (100.0)		55.0000 (0.8286,3650.6911)	10.0000 (0.6710,149.0391)	0.7500 (0.2738,1.0000) 0.0339

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class		Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	
MedDRA Preferred Term	Statistic					p-value[2]	
Eye disorders							
Blindness transient	n (%)	0	1 (50.0)	-	-	-	
				-	-	-	
Seasonal allergy	n (%)	0	1 (50.0)	-	-	-	
				-	-	-	
Endocrine disorders							
Hyperthyroidism	n (%)	0	1 (50.0)	-	-	-	
				-	-	-	

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(Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value[2]
Infections and infestations		n (%)	0	1 (50.0)	-	-	-
					-	-	-
Urinary tract infection		n (%)	0	1 (50.0)	-	-	-
					-	-	-
Gastrointestinal disorders		n (%)	1 (20.0)	0	-	-	-
					-	-	-
Tooth abscess		n (%)	1 (20.0)	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters						
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders	n (%)	1 (20.0)	0	-	-	-
				-	-	-
Hypertension	n (%)	1 (20.0)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

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[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_56

DATE: 16JUL2024 5:43

Table Saf_56

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Interaction
At Least 1 TEAE	p-value [3]	0.0932
Eye disorders	p-value [3]	0.0648

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Zero count correction was applied according to the method proposed by IQWiG.

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_56

DATE: 16JUL2024 5:43

Table Saf_57

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious TEAE	n (%)	1 (9.1)	1 (9.1)	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (9.1)	-	-	-	-
				-	-	-	-
Endophthalmitis	n (%)	0	1 (9.1)	-	-	-	-
				-	-	-	-
Musculoskeletal and connective tissue disorders	n (%)	1 (9.1)	0	-	-	-	-
				-	-	-	-
Back pain	n (%)	1 (9.1)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_57

DATE: 11JUL2024 10:00

Table Saf_57

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious TEAE	n (%)	0	2 (14.3)	-	-	-	-
				-	-	-	-
Eye disorders	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Visual impairment	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-
Lower respiratory tract infection	n (%)	0	1 (7.1)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_57

DATE: 11JUL2024 10:00

Table Saf_57

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious TEAE	n (%)	1 (10.0)	0	-	-	-	-
				-	-	-	-
Musculoskeletal and connective tissue disorders	n (%)	1 (10.0)	0	-	-	-	-
Ankle fracture	n (%)	1 (10.0)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_57

DATE: 11JUL2024 10:00

Table Saf_57

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious TEAE	n (%)	0	1 (50.0)	-	-	-	-
				-	-	-	-
Eye disorders	n (%)	0	1 (50.0)	-	-	-	-
				-	-	-	-
Blindness transient	n (%)	0	1 (50.0)	-	-	-	-
				-	-	-	-
Investigations	n (%)	0	1 (50.0)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_57

DATE: 11JUL2024 10:00

Table Saf_57

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Investigations							
Intraocular pressure increased	n (%)	0	1 (50.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_57

DATE: 11JUL2024 10:00

Table Saf_58

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference
MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	(Masked Data)[1] (N=11)			95% CI p-value
At Least 1 TEAE Related to Study Medication Administration Procedure	n (%)	2 (18.2)	4 (36.4)	- -	- -	- -
Eye disorders	n (%)	2 (18.2)	3 (27.3)	- -	- -	- -
Conjunctival haemorrhage	n (%)	0	2 (18.2)	- -	- -	- -
Corneal scar	n (%)	0	1 (9.1)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_58

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI p-value
Eye disorders							
Eye pain		n (%)	0	1 (9.1)	-	-	-
					-	-	-
Abnormal sensation in eye		n (%)	1 (9.1)	0	-	-	-
					-	-	-
Lacrimation increased		n (%)	1 (9.1)	0	-	-	-
					-	-	-
Infections and infestations		n (%)	0	1 (9.1)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_58

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations						
Endophthalmitis	n (%)	0	1 (9.1)	- -	- -	- -
General disorders and administration site conditions	n (%)	1 (9.1)	0	- -	- -	- -
Injection site pain	n (%)	1 (9.1)	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_58

DATE: 11JUL2024 10:36

Table Saf_58

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference
MedDRA Preferred Term	Statistic	Ranibizumab (N=4)	(Masked Data)[1] (N=14)			95% CI p-value
At Least 1 TEAE Related to Study Medication Administration Procedure	n (%)	1 (25.0)	4 (28.6)	-	-	-
Eye disorders	n (%)	1 (25.0)	4 (28.6)	-	-	-
Conjunctival haemorrhage	n (%)	1 (25.0)	2 (14.3)	-	-	-
Eye pain	n (%)	0	1 (7.1)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_58

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Eye disorders						
Keratopathy	n (%)	0	1 (7.1)	-	-	-
				-	-	-
Punctate keratitis	n (%)	0	1 (7.1)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_58

DATE: 11JUL2024 10:36

Table Saf_58

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value
At Least 1 TEAE Related to Study Medication Administration Procedure	n (%)	3 (30.0)	0	-	-	-	-
Eye disorders	n (%)	1 (10.0)	0	-	-	-	-
Conjunctival haemorrhage	n (%)	1 (10.0)	0	-	-	-	-
General disorders and administration site conditions	n (%)	1 (10.0)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_58

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
General disorders and administration site conditions							
Injection site pain	n (%)	1 (10.0)	0	-	-	-	-
				-	-	-	-
Investigations	n (%)	1 (10.0)	0	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	1 (10.0)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_58

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference
MedDRA Preferred Term	Statistic	Ranibizumab (N=5)	(Masked Data)[1] (N=2)			95% CI p-value
At Least 1 TEAE Related to Study Medication Administration Procedure	n (%)	0	1 (50.0)	- -	- -	- -
Eye disorders	n (%)	0	1 (50.0)	- -	- -	- -
Blindness transient	n (%)	0	1 (50.0)	- -	- -	- -
Investigations	n (%)	0	1 (50.0)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_58

Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Investigations							
Intraocular pressure increased	n (%)	0	1 (50.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_58

DATE: 11JUL2024 10:36

Table Saf_59

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 TEAE Related to Study Drug	n (%)	3 (27.3)	2 (18.2)	-	-	-
Eye disorders	n (%)	3 (27.3)	1 (9.1)	-	-	-
Eye pain	n (%)	0	1 (9.1)	-	-	-
Abnormal sensation in eye	n (%)	1 (9.1)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_59

DATE: 13JUL2024 12:28

Table Saf_59

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Eye disorders						
Cataract	n (%)	1 (9.1)	0	-	-	-
				-	-	-
Lacrimation increased	n (%)	1 (9.1)	0	-	-	-
				-	-	-
Infections and infestations	n (%)	0	1 (9.1)	-	-	-
				-	-	-
Endophthalmitis	n (%)	0	1 (9.1)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_59

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	(Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI p-value
General disorders and administration site conditions	n (%)	1 (9.1)	0	-	-	-
Injection site pain	n (%)	1 (9.1)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_59

DATE: 13JUL2024 12:28

Table Saf_59

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters

MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=10)	(Masked Data)[1] (N=4)			
At Least 1 TEAE Related to Study Drug	n (%)	1 (10.0)	0	-	-	-
Investigations	n (%)	1 (10.0)	0	-	-	-
Intraocular pressure increased	n (%)	1 (10.0)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_59

DATE: 13JUL2024 12:28

Table Saf_59

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 TEAE Related to Study Drug	n (%)	0	1 (50.0)	-	-	-
Eye disorders	n (%)	0	1 (50.0)	-	-	-
Blindness transient	n (%)	0	1 (50.0)	-	-	-
Investigations	n (%)	0	1 (50.0)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_59

Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Investigations						
Intraocular pressure increased	n (%)	0	1 (50.0)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_59

DATE: 13JUL2024 12:28

Table Saf_60

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	3 (27.3)	4 (36.4)	-	-	-
Eye disorders	n (%)	3 (27.3)	3 (27.3)	-	-	-
Conjunctival haemorrhage	n (%)	0	2 (18.2)	-	-	-
Corneal scar	n (%)	0	1 (9.1)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_60

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Eye disorders						
Eye pain	n (%)	0	1 (9.1)	-	-	-
				-	-	-
Abnormal sensation in eye	n (%)	1 (9.1)	0	-	-	-
				-	-	-
Cataract	n (%)	1 (9.1)	0	-	-	-
				-	-	-
Lacrimation increased	n (%)	1 (9.1)	0	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_60

DATE: 13JUL2024 12:35

Table Saf_60

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations	n (%)	0	1 (9.1)	-	-	-
Endophthalmitis	n (%)	0	1 (9.1)	-	-	-
General disorders and administration site conditions	n (%)	1 (9.1)	0	-	-	-
Injection site pain	n (%)	1 (9.1)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_60

DATE: 13JUL2024 12:35

Table Saf_60

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	1 (25.0)	4 (28.6)	-	-	-
Eye disorders	n (%)	1 (25.0)	4 (28.6)	-	-	-
Conjunctival haemorrhage	n (%)	1 (25.0)	2 (14.3)	-	-	-
Eye pain	n (%)	0	1 (7.1)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_60

DATE: 13JUL2024 12:35

Table Saf_60

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters

MedDRA System Organ Class	MedDRA Preferred Term	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders							
	Keratopathy	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Punctate keratitis	n (%)	0	1 (7.1)	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_60

DATE: 13JUL2024 12:35

Table Saf_60

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	3 (30.0)	0	-	-	-
Eye disorders	n (%)	1 (10.0)	0	-	-	-
Conjunctival haemorrhage	n (%)	1 (10.0)	0	-	-	-
General disorders and administration site conditions	n (%)	1 (10.0)	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_60

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters

MedDRA System Organ Class			ONS-5010				Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=10)	(Masked Data)[1] (N=4)	Odds Ratio	Relative Risk	95% CI	Difference
				95% CI	95% CI		95% CI
General disorders and administration site conditions							p-value
Injection site pain	n (%)	1 (10.0)	0	-	-	-	-
				-	-	-	-
Investigations	n (%)	1 (10.0)	0	-	-	-	-
				-	-	-	-
Intraocular pressure increased	n (%)	1 (10.0)	0	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_60

DATE: 13JUL2024 12:35

Table Saf_60

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	0	1 (50.0)	-	-	-
Eye disorders	n (%)	0	1 (50.0)	-	-	-
Blindness transient	n (%)	0	1 (50.0)	-	-	-
Investigations	n (%)	0	1 (50.0)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_60

Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value
and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations						
Intraocular pressure increased	n (%)	0	1 (50.0)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_60

DATE: 13JUL2024 12:35

Table Saf_61

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=11)	(Masked Data)[1] (N=11)			
At Least 1 Serious TEAE Related to Study Drug	n (%)	0	1 (9.1)	-	-	-
				-	-	-
Infections and infestations	n (%)	0	1 (9.1)	-	-	-
				-	-	-
Endophthalmitis	n (%)	0	1 (9.1)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_61

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters						
MedDRA System Organ Class		ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term	Statistic	Ranibizumab (N=5)	(Masked Data)[1] (N=2)			
At Least 1 Serious TEAE Related to Study Drug	n (%)	0	1 (50.0)	-	-	-
				-	-	-
Eye disorders	n (%)	0	1 (50.0)	-	-	-
				-	-	-
Blindness transient	n (%)	0	1 (50.0)	-	-	-
				-	-	-
Investigations	n (%)	0	1 (50.0)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_61

DATE: 13JUL2024 12:40

Table Saf_61

Serious Study Procedure Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Investigations							
Intraocular pressure increased	n (%)	0	1 (50.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug (ONS-5010 or Ranibizumab) per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_62

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
MedDRA Preferred Term							
At Least 1 Serious TEAE Related to Study Medication Administration Procedure	n (%)	0	1 (9.1)	-	-	-	-
				-	-	-	-
Infections and infestations	n (%)	0	1 (9.1)	-	-	-	-
				-	-	-	-
Endophthalmitis	n (%)	0	1 (9.1)	-	-	-	-
				-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_62

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 Serious TEAE Related to Study Medication Administration Procedure	n (%)	0	1 (50.0)	-	-	-	-
Eye disorders	n (%)	0	1 (50.0)	-	-	-	-
Blindness transient	n (%)	0	1 (50.0)	-	-	-	-
Investigations	n (%)	0	1 (50.0)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_62

Serious Study Drug Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
Investigations						
Intraocular pressure increased	n (%)	0	1 (50.0)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_62

DATE: 13JUL2024 12:56

Table Saf_63

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
At Least 1 Serious TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	0	1 (9.1)	-	-	-
				-	-	-
Infections and infestations	n (%)	0	1 (9.1)	-	-	-
				-	-	-
Endophthalmitis	n (%)	0	1 (9.1)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_63

DATE: 13JUL2024 13:14

Table Saf_63

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters

MedDRA System Organ Class	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
MedDRA Preferred Term						
At Least 1 Serious TEAE Related to Either Study Drug or Study Medication Administration Procedure	n (%)	0	1 (50.0)	-	-	-
Eye disorders	n (%)	0	1 (50.0)	-	-	-
Blindness transient	n (%)	0	1 (50.0)	-	-	-
Investigations	n (%)	0	1 (50.0)	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_63

Serious Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters

MedDRA System Organ Class			ONS-5010			Absolute Risk
MedDRA Preferred Term	Statistic	Ranibizumab (N=5)	(Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Difference 95% CI p-value
Investigations						
Intraocular pressure increased	n (%)	0	1 (50.0)	-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Related events are those identified as definitely, probably, or possibly related to study drug or study medication administration procedure per investigator.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_63

DATE: 13JUL2024 13:14

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE		n (%)	5 (45.5)	9 (81.8)	5.4000 (0.7775,37.5046)	1.8000 (0.8896,3.6420)	0.3636 (-0.0086,0.7358) 0.0833
Eye disorders	Grade 1	n (%)	3 (27.3)	5 (45.5)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (9.1)	1 (9.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	0	2 (18.2)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	1 (9.1)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blepharitis	Grade 1	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Corneal scar	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Dry eye	Grade 1	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eye pain	Grade 1	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lenticular opacities	Grade 1	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Vitreous detachment	Grade 1	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Abnormal sensation in eye	Grade 1	n (%)	1 (9.1)	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Cataract	Grade 1	n (%)	1 (9.1)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	1 (9.1)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Investigations	Grade 1	n (%)	0	4 (36.4)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	0	3 (27.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood albumin increased	Grade 1	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood creatinine increased	Grade 1	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood pressure systolic increased	Grade 1	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea increased	Grade 1	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cells urine positive	Grade 1	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 5:44

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Infections and infestations	Grade 1	n (%)	0	1 (9.1)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	1 (9.1)	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term	Grade						
Infections and infestations							
Endophthalmitis	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Influenza	Grade 1	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	1 (9.1)	-	-	-	-
	Grade 3	n (%)	1 (9.1)	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 3	n (%)	1 (9.1)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Immune system disorders	Grade 1	n (%)	0	1 (9.1)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Immune system disorders							
Seasonal allergy	Grade 1	n (%)	0	1 (9.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Metabolism and nutrition disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	1 (9.1)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Hypercholesterolemia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Metabolism and nutrition disorders							
Type 2 diabetes mellitus	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Previous Anti VEGF Therapy: Yes and <=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	0	1 (9.1)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Confusional state	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (9.1)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	1 (9.1)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Injury, poisoning and procedural complications	Grade 1	n (%)	1 (9.1)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Contusion	Grade 1	n (%)	1 (9.1)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE		n (%)	2 (50.0)	11 (78.6)	3.6667 (0.3535,38.0285)	1.5714 (0.5681,4.3468)	0.2857 (-0.2493,0.8208) 0.2742
Eye disorders	Grade 1	n (%)	1 (25.0)	4 (28.6)	-	-	-
					-	-	-
	Grade 2	n (%)	0	2 (14.3)	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (7.1)	-	-	-
					-	-	-
Grade 4	n (%)	0	0		-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	1 (25.0)	2 (14.3)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Posterior capsule opacification	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	2 (14.3)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

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Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Eye pain	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Keratopathy	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Punctate keratitis	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
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Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Subretinal fluid	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (7.1)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Visual impairment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blepharitis	Grade 1	n (%)	1 (25.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 16JUL2024 5:44

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Scleromalacia	Grade 1	n (%)	1 (25.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations	Grade 1	n (%)	0	3 (21.4)	-	-	-
	Grade 2	n (%)	1 (25.0)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Protein urine present	Grade 1	n (%)	0	1 (7.1)	-	-	-
	Grade 2	n (%)	1 (25.0)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	1 (25.0)	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood creatinine increased	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Platelet morphology abnormal	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Red blood cell rouleaux formation present	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Urinary casts	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Infections and infestations	Grade 1	n (%)	0	2 (14.3)	-	-	-	-
	Grade 2	n (%)	0	1 (7.1)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	2 (14.3)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Candida infection	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Kidney infection	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Tooth infection	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Blood and lymphatic system disorders	Grade 1	n (%)	0	2 (14.3)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Lymphadenopathy	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Blood and lymphatic system disorders							
Macrocytosis	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Renal and urinary disorders	Grade 1	n (%)	0	2 (14.3)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Glycosuria	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Renal and urinary disorders							
Renal tubular acidosis	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data) (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (25.0)	1 (7.1)	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Basal cell carcinoma	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (25.0)	1 (7.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Gastrointestinal disorders	Grade 1	n (%)	0	1 (7.1)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Diarrhoea	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Injury, poisoning and procedural complications	Grade 1	n (%)	0	1 (7.1)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Injury, poisoning and procedural complications							
Macular scar	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	1 (7.1)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Rheumatoid arthritis	Grade 1	n (%)	0	1 (7.1)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Previous Anti VEGF Therapy: Yes and >=68 letters								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Vascular disorders	Grade 1	n (%)	0	1 (7.1)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Dizziness	Grade 1	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	1 (25.0)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders							
Brow ptosis	Grade 1	n (%)	1 (25.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE		n (%)	10 (100.0)	3 (75.0)	NE (NE,NE)	0.7500 (0.4259,1.3206)	-0.2500 (-0.6743,0.1743) 0.1138
Eye disorders	Grade 1	n (%)	3 (30.0)	1 (25.0)	-	-	-
					-	-	-
	Grade 2	n (%)	3 (30.0)	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (10.0)	0	-	-	-
					-	-	-
Grade 4	n (%)	0	0		-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Visual acuity reduced	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	2 (20.0)	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctival haemorrhage	Grade 1	n (%)	1 (10.0)	1 (25.0)	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
MedDRA Preferred Term							
Eye disorders							
Neovascular	Grade 1	n (%)	1 (10.0)	0	-	-	-
age-related					-	-	-
macular					-	-	-
degeneration	Grade 2	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Previous Anti VEGF Therapy: No and <=67 letters

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Choroidal neovascularisation	Grade 1	n (%)	0	1 (25.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Conjunctivitis	Grade 1	n (%)	0	1 (25.0)	-	-	-
allergic					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Diabetic retinal oedema	Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Lacrimation increased	Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Previous Anti VEGF Therapy: No and <=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Investigations	Grade 1	n (%)	5 (50.0)	1 (25.0)	-	-	-	
					-	-	-	
	Grade 2	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	0	0	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Eosinophil count increased	Grade 1	n (%)	1 (10.0)	1 (25.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea increased	Grade 1	n (%)	2 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood triglycerides increased	Grade 1	n (%)	0	1 (25.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Aspartate aminotransferase increased	Grade 1	n (%)	1 (10.0)	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood glucose increased	Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters

MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood lactate dehydrogenase increased	Grade 1	n (%)	1 (10.0)	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood sodium increased	Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Intraocular pressure increased	Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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DATE: 16JUL2024 5:44

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Platelet count decreased	Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Infections and infestations	Grade 1	n (%)	3 (30.0)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Influenza	Grade 1	n (%)	2 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Conjunctivitis	Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Lower respiratory tract infection	Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	1 (10.0)	0	-	-	-
	Grade 2	n (%)	2 (20.0)	0	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Ankle fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Back pain	Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Musculoskeletal and connective tissue disorders							
Wrist fracture	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters								
MedDRA System Organ Class	Maximum CTCAE	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Gastrointestinal disorders	Grade 1	n (%)	1 (10.0)	1 (25.0)	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Pancreatitis	Grade 1	n (%)	0	1 (25.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Vomiting	Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
General disorders and administration site conditions	Grade 1	n (%)	1 (10.0)	0	-	-	-	
					-	-	-	
	Grade 2	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 3	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 4	n (%)	0	0	-	-	-	
					-	-	-	
	Grade 5	n (%)	0	0	-	-	-	
					-	-	-	

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
General disorders and administration site conditions							
Injection site pain	Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
Grade 4	n (%)	0	0		-	-	-
					-	-	-
Grade 5	n (%)	0	0		-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Psychiatric disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (10.0)	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Psychiatric disorders							
Insomnia	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Skin and subcutaneous tissue disorders	Grade 1	n (%)	1 (10.0)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Skin and subcutaneous tissue disorders	Skin laceration Grade 1	n (%)	1 (10.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
At Least 1 TEAE		n (%)	3 (60.0)	2 (100.0)	NE (NE, NE)	1.6667 (0.8148, 3.4093)	0.4000 (-0.0294, 0.8294) 0.3272
Investigations	Grade 1	n (%)	2 (40.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (50.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
White blood cells urine positive	Grade 1	n (%)	2 (40.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations Intraocular pressure increased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (50.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood creatinine increased	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Previous Anti VEGF Therapy: No and >=68 letters

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood triglycerides increased	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Investigations							
Blood urea increased	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Eye disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	1 (50.0)	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	1 (50.0)	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Blindness	Grade 1	n (%)	0	0	-	-	-
transient							
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (50.0)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Eye disorders							
Seasonal allergy	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (50.0)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Endocrine disorders	Grade 1	n (%)	0	1 (50.0)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Endocrine disorders							
Hyperthyroidism	Grade 1	n (%)	0	1 (50.0)	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

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Previous Anti VEGF Therapy: No and >=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Infections and infestations	Grade 1	n (%)	0	1 (50.0)	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Infections and infestations							
Urinary tract infection	Grade 1	n (%)	0	1 (50.0)	- -	- -	- -
	Grade 2	n (%)	0	0	- -	- -	- -
	Grade 3	n (%)	0	0	- -	- -	- -
	Grade 4	n (%)	0	0	- -	- -	- -
	Grade 5	n (%)	0	0	- -	- -	- -

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Previous Anti VEGF Therapy: No and >=68 letters								
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]	
Gastrointestinal disorders	Grade 1	n (%)	1 (20.0)	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

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Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Gastrointestinal disorders							
Tooth abscess	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data) (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI	p-value[2]
Vascular disorders	Grade 1	n (%)	1 (20.0)	0	-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

DATE: 16JUL2024 5:44

Date of data extract: 26AUG2020

Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class MedDRA Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
Vascular disorders							
Hypertension	Grade 1	n (%)	1 (20.0)	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

NE = Not estimable

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_64

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Table Saf_64

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Interaction
MedDRA Preferred Term		p-value [3]	
At Least 1 TEAE			0.0932

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model. For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE		n (%)	1 (9.1)	1 (9.1)	-	-	-
Infections and infestations	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (9.1)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-
					-	-	-
					-	-	-
					-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_65

DATE: 15JUL2024 4:36

Table Saf_65

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations	Endophthalmitis Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (9.1)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 15JUL2024 4:36

Table Saf_65

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters								
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value	
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 2	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 3	n (%)	1 (9.1)	0	-	-	-	-
					-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
					-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-
					-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Musculoskeletal and connective tissue disorders Back pain							
	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	1 (9.1)	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

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Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_65

DATE: 15JUL2024 4:36

Table Saf_65

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE		n (%)	0	2 (14.3)	-	-	-
Eye disorders	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (7.1)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_65

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Table Saf_65

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders							
Visual impairment	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_65

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Table Saf_65

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	1 (7.1)	-	-	-
					-	-	-
	Grade 3	n (%)	0	0	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 15JUL2024 4:36

Table Saf_65

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Infections and infestations Lower respiratory tract infection	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	1 (7.1)	-	-	-
	Grade 3	n (%)	0	0	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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DATE: 15JUL2024 4:36

Table Saf_65

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters								
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value	
At Least 1 Serious TEAE		n (%)	1 (10.0)	0	-	-	-	-
Musculoskeletal and connective tissue disorders	Grade 1	n (%)	0	0	-	-	-	-
	Grade 2	n (%)	1 (10.0)	0	-	-	-	-
	Grade 3	n (%)	0	0	-	-	-	-
	Grade 4	n (%)	0	0	-	-	-	-
	Grade 5	n (%)	0	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

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Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data)[1] (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Musculoskeletal and connective tissue disorders Ankle fracture	Grade 1	n (%)	0	0	-	-	-
							-
	Grade 2	n (%)	1 (10.0)	0	-	-	-
							-
	Grade 3	n (%)	0	0	-	-	-
							-
	Grade 4	n (%)	0	0	-	-	-
							-
	Grade 5	n (%)	0	0	-	-	-
							-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 Serious TEAE		n (%)	0	1 (50.0)	-	-	-
Eye disorders	Grade 1	n (%)	0	0	-	-	-
	Grade 2	n (%)	0	0	-	-	-
	Grade 3	n (%)	0	1 (50.0)	-	-	-
	Grade 4	n (%)	0	0	-	-	-
	Grade 5	n (%)	0	0	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

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Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Eye disorders							
Blindness transient	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (50.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

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Reference Listing: 16.2.7.1, 16.2.7.2

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Table Saf_65

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (50.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_65

DATE: 15JUL2024 4:36

Table Saf_65

Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term by Maximum CTCAE Severity Grade by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and >=68 letters							
MedDRA System Organ Class Preferred Term	Maximum CTCAE Grade	Statistic	Ranibizumab (N=5)	ONS-5010 (Masked Data)[1] (N=2)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
Investigations							
Intraocular pressure increased	Grade 1	n (%)	0	0	-	-	-
					-	-	-
	Grade 2	n (%)	0	0	-	-	-
					-	-	-
	Grade 3	n (%)	0	1 (50.0)	-	-	-
					-	-	-
	Grade 4	n (%)	0	0	-	-	-
					-	-	-
	Grade 5	n (%)	0	0	-	-	-
					-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0. Toxicity is graded using NCI CTCAE version 4.03. CTCAE = Common Terminology Criteria for Adverse Events.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup. In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_65

DATE: 15JUL2024 4:36

Table Saf_66

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	0	2 (18.2)	-	-	-	-
Eye disorders	n (%)	0	1 (9.1)	-	-	-	-
Visual acuity reduced	n (%)	0	1 (9.1)	-	-	-	-
Infections and infestations	n (%)	0	1 (9.1)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_66

DATE: 14JUL2024 9:40

Table Saf_66

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=11)	ONS-5010 (Masked Data)[1] (N=11)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
Infections and infestations							
Endophthalmitis	n (%)	0	1 (9.1)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_66

DATE: 14JUL2024 9:40

Table Saf_66

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: Yes and >=68 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=4)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI		95% CI p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	0	1 (7.1)	-	-	-	-
Eye disorders	n (%)	0	1 (7.1)	-	-	-	-
Subretinal fluid	n (%)	0	1 (7.1)	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_66

DATE: 14JUL2024 9:40

Table Saf_66

Treatment-Emergent Adverse Events Leading to Study Withdrawal by MedDRA System Organ Class and Preferred Term by Baseline BCVA Value and Prior anti-VEGF in NORSE-1 Study (Safety Population)

Previous Anti VEGF Therapy: No and <=67 letters							Absolute Risk Difference
MedDRA System Organ Class	Statistic	Ranibizumab (N=10)	ONS-5010 (Masked Data) (N=4)	Odds Ratio 95% CI	Relative Risk 95% CI	95% CI	p-value
At Least 1 TEAE Leading to Study Withdrawal	n (%)	3 (30.0)	0	-	-	-	-
Eye disorders	n (%)	3 (30.0)	0	-	-	-	-
Visual acuity reduced	n (%)	3 (30.0)	0	-	-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

In case of zero observations for both treatment groups, results are not shown, i.e. these tables only include cases with at least one observation in one treatment group

Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_66

DATE: 14JUL2024 9:40

Table Saf_97

Severe AE (CTCAE Grade ≥ 3) by Age in NORSE-1 Study
(Safety Population)

< 80 years						
Parameter	Statistic	Ranibizumab (N=17)	ONS-5010 (Masked Data)[1] (N=17)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 TEAE(CTCAE Grade ≥ 3)	n (%)	2 (11.8)	2 (11.8)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_97

Severe AE (CTCAE Grade ≥ 3) by Age in NORSE-1 Study
 (Safety Population)

≥ 80 years						
Parameter	Statistic	Ranibizumab (N=13)	ONS-5010 (Masked Data)[1] (N=14)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 TEAE(CTCAE Grade ≥ 3)	n (%)	0	2 (14.3)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_97

Severe AE (CTCAE Grade ≥ 3) by Age in NORSE-1 Study
(Safety Population)

Parameter	Statistic	Interaction
At Least 1 TEAE(CTCAE Grade ≥ 3)	p-value	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_97

DATE: 16SEP2024 11:42

Table Saf_98

Severe AE (CTCAE Grade >=3) by Gender in NORSE-1 Study
 (Safety Population)

Male						
Parameter	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=9)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 TEAE(CTCAE Grade >=3)	n (%)	1 (6.7)	0	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_98

Severe AE (CTCAE Grade >=3) by Gender in NORSE-1 Study
(Safety Population)

Female						
Parameter	Statistic	ONS-5010		Odds Ratio	Relative Risk	Absolute Risk
		Ranibizumab (N=15)	(Masked Data)[1] (N=22)			Difference
At Least 1 TEAE(CTCAE Grade >=3)	n (%)	1 (6.7)	4 (18.2)	95% CI	95% CI	95% CI p-value
				-	-	-
				-	-	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_98

Severe AE (CTCAE Grade ≥ 3) by Gender in NORSE-1 Study
(Safety Population)

Parameter	Statistic	Interaction
At Least 1 TEAE(CTCAE Grade ≥ 3)	p-value	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_98

DATE: 16SEP2024 11:51

Table Saf_99

Severe AE (CTCAE Grade ≥ 3) by Previous Anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes						
Parameter	Statistic	Ranibizumab (N=15)	ONS-5010 (Masked Data)[1] (N=25)	Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
At Least 1 TEAE(CTCAE Grade ≥ 3)	n (%)	1 (6.7)	3 (12.0)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_99

Severe AE (CTCAE Grade ≥ 3) by Previous Anti-VEGF in NORSE-1 Study
 (Safety Population)

Previous Anti VEGF Therapy: No						
Parameter	Statistic	ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value
		Ranibizumab (N=15)	(Masked Data)[1] (N=6)			
At Least 1 TEAE(CTCAE Grade ≥ 3)	n (%)	1 (6.7)	1 (16.7)	- -	- -	- -

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_99

Severe AE (CTCAE Grade ≥ 3) by Previous Anti-VEGF in NORSE-1 Study
(Safety Population)

Parameter	Statistic	Interaction
At Least 1 TEAE(CTCAE Grade ≥ 3)	p-value	-

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.
For binary endpoints subgroup analysis will only be performed, if there are at least 10 patients with the event of interest in at least one subgroup.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_99

DATE: 16SEP2024 11:56

Table Saf_104

Non-Severe AE (CTCAE Grade <3) by Age in NORSE-1 Study
(Safety Population)

< 80 years						
Parameter	Statistic	ONS-5010		Odds Ratio	Relative Risk	Absolute Risk
		Ranibizumab (N=17)	(Masked Data)[1] (N=17)			Difference
At Least 1 TEAE(CTCAE Grade <3)	n (%)	13 (76.5)	14 (82.4)	1.4359 (0.2685, 7.6777)	1.0769 (0.7639,1.5182)	0.0588 (-0.2123,0.3299) 0.6761

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_104

Non-Severe AE (CTCAE Grade <3) by Age in NORSE-1 Study
 (Safety Population)

>= 80 years						
Parameter	Statistic	ONS-5010		Odds Ratio	Relative Risk	Absolute Risk Difference
		Ranibizumab (N=13)	(Masked Data)[1] (N=14)			
At Least 1 TEAE(CTCAE Grade <3)	n (%)	7 (53.8)	11 (78.6)	3.1429 (0.5864, 16.8448)	1.4592 (0.8229, 2.5875)	0.2473 (-0.0986, 0.5931) 0.1814

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_104

Non-Severe AE (CTCAE Grade <3) by Age in NORSE-1 Study
(Safety Population)

Parameter	Statistic	Interaction
At Least 1 TEAE(CTCAE Grade <3)	p-value [3]	0.5113

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_104

DATE: 16SEP2024 12:01

Table Saf_105

Non-Severe AE (CTCAE Grade <3) by Gender in NORSE-1 Study
(Safety Population)

Male						
Parameter	Statistic	ONS-5010		Odds Ratio	Relative Risk	Absolute Risk Difference
		Ranibizumab (N=15)	(Masked Data) (N=9)			
At Least 1 TEAE(CTCAE Grade <3)	n (%)	8 (53.3)	7 (77.8)	3.0625 (0.4718, 19.8788)	1.4583 (0.8098, 2.6262)	0.2444 (-0.1264, 0.6153) 0.2411

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_105

Non-Severe AE (CTCAE Grade <3) by Gender in NORSE-1 Study
 (Safety Population)

Female						
Parameter	Statistic	ONS-5010		Odds Ratio	Relative Risk	Absolute Risk
		Ranibizumab (N=15)	(Masked Data) (N=22)			Difference
At Least 1 TEAE(CTCAE Grade <3)	n (%)	12 (80.0)	18 (81.8)	1.1250 (0.2127, 5.9502)	1.0227 (0.7422,1.4094)	0.0182 (-0.2406,0.2769) 0.8912

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_105

Non-Severe AE (CTCAE Grade <3) by Gender in NORSE-1 Study
(Safety Population)

Parameter	Statistic	Interaction
At Least 1 TEAE(CTCAE Grade <3)	p-value [3]	0.4425

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_105

DATE: 16SEP2024 12:09

Table Saf_106

Non-Severe AE (CTCAE Grade <3) by Previous Anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: Yes						
Parameter	Statistic	ONS-5010		Odds Ratio 95% CI	Relative Risk 95% CI	Absolute Risk Difference 95% CI p-value[2]
		Ranibizumab (N=15)	(Masked Data)[1] (N=25)			
At Least 1 TEAE(CTCAE Grade <3)	n (%)	7 (46.7)	20 (80.0)	4.5714 (1.1156,18.7325)	1.7143 (0.9642,3.0478)	0.3333 (0.0361,0.6305) 0.0314

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_106

Non-Severe AE (CTCAE Grade <3) by Previous Anti-VEGF in NORSE-1 Study
(Safety Population)

Previous Anti VEGF Therapy: No						
Parameter	Statistic	ONS-5010		Odds Ratio	Relative Risk	Absolute Risk Difference
		Ranibizumab (N=15)	(Masked Data) (N=6)			
At Least 1 TEAE(CTCAE Grade <3)	n (%)	13 (86.7)	5 (83.3)	0.7692 (0.0564,10.4886)	0.9615 (0.6386,1.4477)	-0.0333 (-0.3776,0.3109) 0.8474

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[1] Data obtained while subjects' randomization assignment were masked to the evaluating physician through the first 11 months of safety follow-up.

[2] p-value was calculated using PROC FREQ by Cochran-Mantel-Haenszel method.

Odds Ratio, Relative Risk and Absolute Risk Difference estimate with the corresponding asymptotic 95% CIs were calculated using PROC FREQ.

Reference Listing: 16.2.7.1, 16.2.7.2

Table Saf_106

Non-Severe AE (CTCAE Grade <3) by Previous Anti-VEGF in NORSE-1 Study
(Safety Population)

Parameter	Statistic	Interaction
At Least 1 TEAE(CTCAE Grade <3)	p-value [3]	0.0373

Note: TEAE = Treatment-Emergent Adverse Event. Adverse events are coded using MedDRA version 23.0.

[3] p-value for the interaction term between subgroup and treatment was calculated using PROC LOGISTIC by subgroup*treatment model.
Reference Listing: 16.2.7.1, 16.2.7.2

PROGRAM NAME: AMNOG-OutlookTherapeutics-Norse/AMNOG/Code/Tables/Saf_106

DATE: 16SEP2024 12:15