Zuranolon (Zurzuvae™)

Biogen GmbH

Anhang 4-H zu Modul 4 A
Ergebnisse der Studie ROBIN

Behandlung von Erwachsenen mit postpartaler Depression (PPD) nach Entbindung

Stand: 15.07.2026

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1 Baseline Charakteristika

1.1 Dargestellt nach der ITT-Population

Summary of Demographics and Baseline Characteristics: 217-PPD-201B - ITT population

Page: 1 of 6

Variable Statistic or Category	Placebo (N=76)	Zuranolone (N=77)	Total (N=153)
Age at informed consent date (years)			
n	76	77	153
Mean (SD)	27.3 (5.29)	29.2 (5.39)	28.3 (5.41)
Median	27.5	29.0	28.0
Q1, Q3	23.0, 31.5	25.0, 33.0	24.0, 33.0
Min, Max	18, 38	18, 44	18, 44
Age at informed consent date (years) - Category, n (%)			
n [1]	76	77	153
18-24 years	26 (34.2)	18 (23.4)	44 (28.8)
25-45 years	50 (65.8)	59 (76.6)	109 (71.2)
Ethnicity, n (%)			
n [1]	76	77	153
Not Hispanic or Latino	58 (76.3)	60 (77.9)	118 (77.1)
Hispanic or Latino	18 (23.7)	17 (22.1)	35 (22.9)

Abbreviations: SD = Standard Deviation; Min = Minimum; Max = Maximum; BMI = Body Mass Index.
[1] Used as the denominator of percentage for the respective section.
Source: biib125/v_a/germany_amnog/t-demog.sas:t-demog-201-itta.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-201B - ITT population

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Variable Statistic or Category	Placebo (N=76)	Zuranolone (N=77)	Total (N=153)
Race, n (%)			
n [1]	76	77	153
White	40 (52.6)	45 (58.4)	85 (55.6)
Black or African American	33 (43.4)	31 (40.3)	64 (41.8)
More than One Race	1 (1.3)	0	1 (0.7)
Other	0	0	0
American Indian or Alaska Native	0	0	0
Asian	1 (1.3)	1 (1.3)	2 (1.3)
Native Hawaiian or Other Pacific Islander	1 (1.3)	0	1 (0.7)
Not Reported	0	0	0
Race - Category, n (%)			
n [1]	76	77	153
Black or African American	33 (43.4)	31 (40.3)	64 (41.8)
White	40 (52.6)	45 (58.4)	85 (55.6)
Other	3 (3.9)	1 (1.3)	4 (2.6)
Country, n (%)			
n [1]	76	77	153
US	76 (100)	77 (100)	153 (100)
Rest of World	0	0	0

Abbreviations: SD = Standard Deviation; Min = Minimum; Max = Maximum; BMI = Body Mass Index.

[1] Used as the denominator of percentage for the respective section.

Source: biib125/v_a/germany_amnog/t-demog.sas:t-demog-201-itta.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-201B - ITT population

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Variable Statistic or Category	Placebo (N=76)	Zuranolone (N=77)	Total (N=153)
Height (cm)			
n	75	76	151
Mean (SD)	162.44 (7.130)	164.98 (7.429)	163.72 (7.369)
Median	162.56	164.85	163.00
Q1, Q3	157.50, 167.60	160.02, 170.00	159.00, 169.00
Min, Max	147.3, 181.0	147.3, 185.4	147.3, 185.4
Weight (kg)			
n	75	76	151
Mean (SD)	79.94 (23.546)	85.06 (19.104)	82.52 (21.508)
Median	77.40	85.95	81.10
Q1, Q3	62.30, 96.00	70.35, 97.18	64.86, 97.07
Min, Max	44.5, 172.4	49.5, 144.2	44.5, 172.4
BMI (kg/m^2)			
n	75	76	151
Mean (SD)	30.17 (8.087)	31.14 (6.218)	30.66 (7.199)
Median	28.50	30.65	30.00
Q1, Q3	23.40, 36.30	26.45, 34.60	25.40, 35.10
Min, Max	16.5, 56.1	19.6, 47.2	16.5, 56.1

Abbreviations: SD = Standard Deviation; Min = Minimum; Max = Maximum; BMI = Body Mass Index.

[1] Used as the denominator of percentage for the respective section.

Source: biib125/v_a/germany_amnog/t-demog.sas:t-demog-201-itta.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-201B - ITT population

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Variable Statistic or Category	Placebo (N=76)	Zuranolone (N=77)	Total (N=153)
BMI (kg/m^2) - Category, n (%)			
n [1]	75	76	151
<=18.4	2 (2.7)	0	2 (1.3)
18.5-24.9	19 (25.3)	13 (17.1)	32 (21.2)
25-29.9	20 (26.7)	21 (27.6)	41 (27.2)
>=30	34 (45.3)	42 (55.3)	76 (50.3)
BMI (kg/m^2) - Category 2, n (%)			
n [1]	75	76	151
<=24.9	21 (28.0)	13 (17.1)	34 (22.5)
25-29.9	20 (26.7)	21 (27.6)	41 (27.2)
>=30	34 (45.3)	42 (55.3)	76 (50.3)
Baseline antidepressant use, n (%)			
n [1]	76	77	153
Yes	13 (17.1)	16 (20.8)	29 (19.0)
No	63 (82.9)	61 (79.2)	124 (81.0)

Abbreviations: SD = Standard Deviation; Min = Minimum; Max = Maximum; BMI = Body Mass Index.

[1] Used as the denominator of percentage for the respective section.

Source: biib125/v_a/germany_amnog/t-demog.sas:t-demog-201-itta.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-201B - ITT population

Page: 5 of 6

Variable Statistic or Category	Placebo (N=76)	Zuranolone (N=77)	Total (N=153)
Baseline HAMD-17 Total Score - Category, n (%)			
n [1]	75	76	151
<28 (median of baseline HAMD-17 total score)	22 (29.3)	30 (39.5)	52 (34.4)
>=28 (median of baseline HAMD-17 total score)	53 (70.7)	46 (60.5)	99 (65.6)
Onset of PPD, n (%)			
n [1]	76	77	153
3rd Trimester	32 (42.1)	32 (41.6)	64 (41.8)
Postpartum	44 (57.9)	45 (58.4)	89 (58.2)
History of PPD, n (%)			
n [1]	76	77	153
1st Episode	60 (78.9)	67 (87.0)	127 (83.0)
Recurrent Episode	16 (21.1)	10 (13.0)	26 (17.0)

Abbreviations: SD = Standard Deviation; Min = Minimum; Max = Maximum; BMI = Body Mass Index.

[1] Used as the denominator of percentage for the respective section.

Source: biib125/v_a/germany_amnog/t-demog.sas:t-demog-201-itta.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-201B - ITT population

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Variable Statistic or Category	Placebo (N=76)	Zuranolone (N=77)	Total (N=153)
Family History of PPD, n (%)			
n [1]	76	77	153
Yes	10 (13.2)	10 (13.0)	20 (13.1)
No/Unknown	66 (86.8)	67 (87.0)	133 (86.9)
Depression with Elevated Anxiety, by Baseline HAMD-17 Anxiety Subscale, n (%)			
n [1]	75	76	151
>=7 (Normalized Score >=39)	72 (96.0)	74 (97.4)	146 (96.7)
<7 (Normalized Score <39)	3 (4.0)	2 (2.6)	5 (3.3)
Depression with Elevated Anxiety, by Baseline HAMA Total Score, n (%)			
n [1]	75	76	151
>=20	67 (89.3)	66 (86.8)	133 (88.1)
<20	8 (10.7)	10 (13.2)	18 (11.9)
Any antidepressant medication ever taken, n (%)			
n [1]	76	77	153
Yes	20 (26.3)	24 (31.2)	44 (28.8)
No	56 (73.7)	53 (68.8)	109 (71.2)

Abbreviations: SD = Standard Deviation; Min = Minimum; Max = Maximum; BMI = Body Mass Index.

[1] Used as the denominator of percentage for the respective section.

Source: biib125/v_a/germany_amnog/t-demog.sas:t-demog-201-itta.rtf **Run Date:** 11JUL2025

1.2 Dargestellt nach der Safety-Population

Summary of Demographics and Baseline Characteristics: 217-PPD-201B - Safety population

Page: 1 of 6

Variable Statistic or Category	Placebo (N=73)	Zuranolone (N=78)	Total (N=151)
Age at informed consent date (years)			
n	73	78	151
Mean (SD)	27.4 (5.36)	29.2 (5.35)	28.3 (5.41)
Median	28.0	29.0	28.0
Q1, Q3	23.0, 32.0	25.0, 33.0	24.0, 33.0
Min, Max	18, 38	18, 44	18, 44
Age at informed consent date (years) - Category, n (%)			
n [1]	73	78	151
18-24 years	25 (34.2)	17 (21.8)	42 (27.8)
25-45 years	48 (65.8)	61 (78.2)	109 (72.2)
Ethnicity, n (%)			
n [1]	73	78	151
Not Hispanic or Latino	57 (78.1)	60 (76.9)	117 (77.5)
Hispanic or Latino	16 (21.9)	18 (23.1)	34 (22.5)

Abbreviations: SD = Standard Deviation; Min = Minimum; Max = Maximum; BMI = Body Mass Index.
[1] Used as the denominator of percentage for the respective section.
Source: biib125/v_a/germany_amnog/t-demog.sas:t-demog-201-safc.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-201B - Safety population

Page: 2 of 6

Variable Statistic or Category	Placebo (N=73)	Zuranolone (N=78)	Total (N=151)
Race, n (%)			
n [1]	73	78	151
White	39 (53.4)	45 (57.7)	84 (55.6)
Black or African American	32 (43.8)	31 (39.7)	63 (41.7)
More than One Race	0	1 (1.3)	1 (0.7)
Other	0	0	0
American Indian or Alaska Native	0	0	0
Asian	1 (1.4)	1 (1.3)	2 (1.3)
Native Hawaiian or Other Pacific Islander	1 (1.4)	0	1 (0.7)
Not Reported	0	0	0
Race - Category, n (%)			
n [1]	73	78	151
Black or African American	32 (43.8)	31 (39.7)	63 (41.7)
White	39 (53.4)	45 (57.7)	84 (55.6)
Other	2 (2.7)	2 (2.6)	4 (2.6)
Country, n (%)			
n [1]	73	78	151
US	73 (100)	78 (100)	151 (100)
Rest of World	0	0	0

Abbreviations: SD = Standard Deviation; Min = Minimum; Max = Maximum; BMI = Body Mass Index.

[1] Used as the denominator of percentage for the respective section.

Source: biib125/v_a/germany_amnog/t-demog.sas:t-demog-201-safc.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-201B - Safety population

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Variable Statistic or Category	Placebo (N=73)	Zuranolone (N=78)	Total (N=151)
Height (cm)			
n	73	78	151
Mean (SD)	162.32 (6.787)	165.02 (7.690)	163.72 (7.369)
Median	162.56	164.85	163.00
Q1, Q3	158.40, 167.00	160.02, 170.00	159.00, 169.00
Min, Max	147.3, 178.5	147.3, 185.4	147.3, 185.4
Weight (kg)			
n	73	78	151
Mean (SD)	80.25 (23.490)	84.64 (19.385)	82.52 (21.508)
Median	77.40	85.95	81.10
Q1, Q3	62.70, 96.00	70.31, 97.07	64.86, 97.07
Min, Max	44.5, 172.4	45.8, 144.2	44.5, 172.4
BMI (kg/m^2)			
n	73	78	151
Mean (SD)	30.35 (8.098)	30.95 (6.282)	30.66 (7.199)
Median	28.70	30.45	30.00
Q1, Q3	23.60, 36.30	26.40, 34.50	25.40, 35.10
Min, Max	16.5, 56.1	19.6, 47.2	16.5, 56.1

Abbreviations: SD = Standard Deviation; Min = Minimum; Max = Maximum; BMI = Body Mass Index.

[1] Used as the denominator of percentage for the respective section.

Source: biib125/v_a/germany_amnog/t-demog.sas:t-demog-201-safc.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-201B - Safety population

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Variable Statistic or Category	Placebo (N=73)	Zuranolone (N=78)	Total (N=151)
BMI (kg/m^2) - Category, n (%)			
n [1]	73	78	151
<=18.4	2 (2.7)	0	2 (1.3)
18.5-24.9	18 (24.7)	14 (17.9)	32 (21.2)
25-29.9	19 (26.0)	22 (28.2)	41 (27.2)
>=30	34 (46.6)	42 (53.8)	76 (50.3)
BMI (kg/m^2) - Category 2, n (%)			
n [1]	73	78	151
<=24.9	20 (27.4)	14 (17.9)	34 (22.5)
25-29.9	19 (26.0)	22 (28.2)	41 (27.2)
>=30	34 (46.6)	42 (53.8)	76 (50.3)
Baseline antidepressant use, n (%)			
n [1]	73	78	151
Yes	13 (17.8)	16 (20.5)	29 (19.2)
No	60 (82.2)	62 (79.5)	122 (80.8)

Abbreviations: SD = Standard Deviation; Min = Minimum; Max = Maximum; BMI = Body Mass Index.

[1] Used as the denominator of percentage for the respective section.

Source: biib125/v_a/germany_amnog/t-demog.sas:t-demog-201-safc.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-201B - Safety population

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Variable Statistic or Category	Placebo (N=73)	Zuranolone (N=78)	Total (N=151)
Baseline HAMD-17 Total Score - Category, n (%)			
n [1]	73	78	151
<28 (median of baseline HAMD-17 total score)	21 (28.8)	31 (39.7)	52 (34.4)
>=28 (median of baseline HAMD-17 total score)	52 (71.2)	47 (60.3)	99 (65.6)
Onset of PPD, n (%)			
n [1]	73	78	151
3rd Trimester	31 (42.5)	33 (42.3)	64 (42.4)
Postpartum	42 (57.5)	45 (57.7)	87 (57.6)
History of PPD, n (%)			
n [1]	73	78	151
1st Episode	57 (78.1)	68 (87.2)	125 (82.8)
Recurrent Episode	16 (21.9)	10 (12.8)	26 (17.2)

Abbreviations: SD = Standard Deviation; Min = Minimum; Max = Maximum; BMI = Body Mass Index.

[1] Used as the denominator of percentage for the respective section.

Source: biib125/v_a/germany_amnog/t-demog.sas:t-demog-201-safc.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-201B - Safety population

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Variable Statistic or Category	Placebo (N=73)	Zuranolone (N=78)	Total (N=151)
Family History of PPD, n (%)			
n [1]	73	78	151
Yes	10 (13.7)	10 (12.8)	20 (13.2)
No/Unknown	63 (86.3)	68 (87.2)	131 (86.8)
Depression with Elevated Anxiety, by Baseline HAMD-17 Anxiety Subscale, n (%)			
n [1]	73	78	151
>=7 (Normalized Score >=39)	70 (95.9)	76 (97.4)	146 (96.7)
<7 (Normalized Score <39)	3 (4.1)	2 (2.6)	5 (3.3)
Depression with Elevated Anxiety, by Baseline HAMA Total Score, n (%)			
n [1]	73	78	151
>=20	65 (89.0)	68 (87.2)	133 (88.1)
<20	8 (11.0)	10 (12.8)	18 (11.9)
Any antidepressant medication ever taken, n (%)			
n [1]	73	78	151
Yes	19 (26.0)	25 (32.1)	44 (29.1)
No	54 (74.0)	53 (67.9)	107 (70.9)

Abbreviations: SD = Standard Deviation; Min = Minimum; Max = Maximum; BMI = Body Mass Index.
[1] Used as the denominator of percentage for the respective section.
Source: biib125/v_a/germany_amnog/t-demog.sas:t-demog-201-safc.rtf **Run Date:** 11JUL2025

1.3 PPD-Schweregrad

Output 2 Page 5 of 16

Summary of Baseline Subgroups based on MADRS Total Score, EPDS Total Score, CGI-S Score and PHQ-9 Total Score: 217-PPD-201B - ITT population

Page: 1 of 3

	Placebo (N = 76)	Zuranolone (N = 77)	Overall (N = 153)
Baseline MADRS Total Score			
n	75	76	151
Mean	36.3	34.9	35.6
SD	4.67	4.41	4.58
Median	36.0	35.0	36.0
Min, Max	27, 50	26, 45	26, 50
Baseline MADRS Total Score Group, n (%)			
n	75	76	151
20 - 34 (Moderate)	26 (34.7)	36 (47.4)	62 (41.1)
>= 35 (Severe)	49 (65.3)	40 (52.6)	89 (58.9)
Baseline EPDS Total Score			
n	75	76	151
Mean	20.1	19.9	20.0
SD	3.76	3.84	3.79
Median	20.0	19.0	20.0
Min, Max	8, 29	13, 27	8, 29

Abbreviations: CGI-S = Clinical Global Impression - Severity; EPDS = Edinburgh Postpartum Depression Scale; MADRS = Montgomery-Asberg Depression Rating Scale; PHQ-9 = 9-item Patient Health Questionnaire.
NOTE 1: Treatment group percentages are based on n, the number of participants with non-missing data.
[1] Includes 3 zuranolone and 2 placebo participants with a PHQ-9 total score that indicates mild depression.
Source: biib125/v_a/germany_amnog/t-summ-dis-sev.sas:t-summ-dis-sev-201-itta.rtf **Run Date:** 22OCT2025

Summary of Baseline Subgroups based on MADRS Total Score, EPDS Total Score, CGI-S Score and PHQ-9 Total Score: 217-PPD-201B - ITT population

Page: 2 of 3

	Placebo (N = 76)	Zuranolone (N = 77)	Overall (N = 153)
Baseline EPDS Total Score Group, n (%)			
n	75	76	151
< 20	34 (45.3)	39 (51.3)	73 (48.3)
>= 20	41 (54.7)	37 (48.7)	78 (51.7)
Baseline CGI-S Score			
n	75	76	151
Mean	4.9	5.0	4.9
SD	0.52	0.58	0.55
Median	5.0	5.0	5.0
Min, Max	4, 6	4, 6	4, 6
Baseline CGI-S Score Group, n (%)			
n	75	76	151
4 (Moderately Ill)	15 (20.0)	13 (17.1)	28 (18.5)
5 (Markedly Ill)	54 (72.0)	51 (67.1)	105 (69.5)
6 (Severely Ill)	6 (8.0)	12 (15.8)	18 (11.9)

Abbreviations: CGI-S = Clinical Global Impression - Severity; EPDS = Edinburgh Postpartum Depression Scale; MADRS = Montgomery-Asberg Depression Rating Scale; PHQ-9 = 9-item Patient Health Questionnaire.

NOTE 1: Treatment group percentages are based on n, the number of participants with non-missing data.

[1] Includes 3 zuranolone and 2 placebo participants with a PHQ-9 total score that indicates mild depression.

Source: biib125/v_a/germany_amnog/t-summ-dis-sev.sas:t-summ-dis-sev-201-itta.rtf **Run Date:** 22OCT2025

Summary of Baseline Subgroups based on MADRS Total Score, EPDS Total Score, CGI-S Score and PHQ-9 Total Score: 217-PPD-201B - ITT population

Page: 3 of 3

	Placebo (N = 76)	Zuranolone (N = 77)	Overall (N = 153)
Baseline PHQ-9 Total Score			
n	75	76	151
Mean	18.4	18.4	18.4
SD	4.10	4.51	4.29
Median	19.0	19.0	19.0
Min, Max	5, 25	8, 27	5, 27
Baseline PHQ-9 Total Score Group, n (%)			
n	75	76	151
<= 14 (Mild to Moderate Depression) [1]	13 (17.3)	13 (17.1)	26 (17.2)
15-19 (Moderately Severe Depression)	30 (40.0)	32 (42.1)	62 (41.1)
>=20 (Severe Depression)	32 (42.7)	31 (40.8)	63 (41.7)

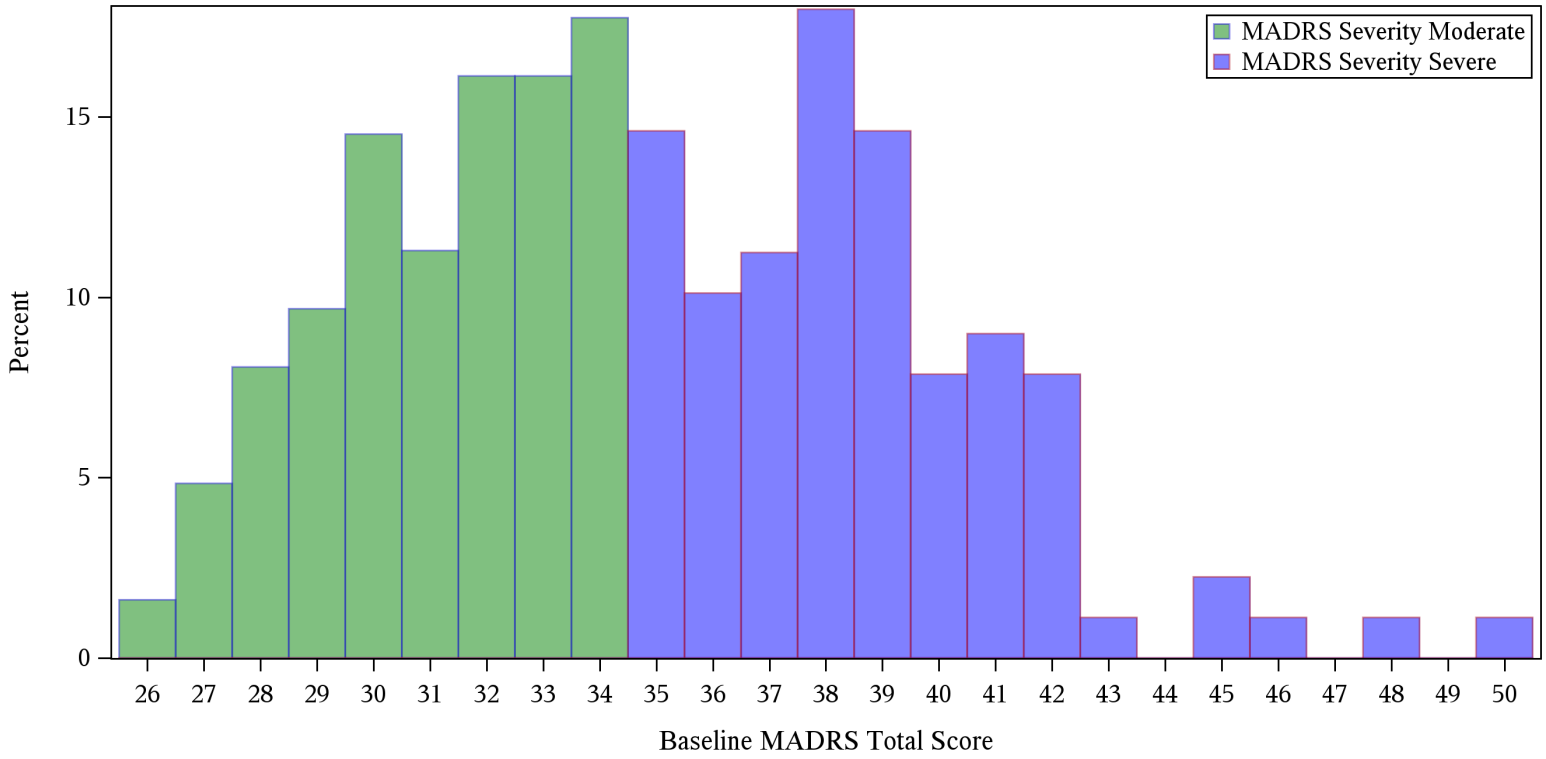
Abbreviations: CGI-S = Clinical Global Impression - Severity; EPDS = Edinburgh Postpartum Depression Scale; MADRS = Montgomery-Asberg Depression Rating Scale; PHQ-9 = 9-item Patient Health Questionnaire.

NOTE 1: Treatment group percentages are based on n, the number of participants with non-missing data.

[1] Includes 3 zuranolone and 2 placebo participants with a PHQ-9 total score that indicates mild depression.

Source: biib125/v_a/germany_amnog/t-summ-dis-sev.sas:t-summ-dis-sev-201-itta.rtf **Run Date:** 22OCT2025

Histogram of Baseline MADRS Total Score by Baseline MADRS Severity: 217-PPD-201B - ITT population
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Source: biib125/v_a/germany_amnog/f-hist-madrs.sas:f-hist-madrs-201-itta.rtf **Run Date:** 02OCT2025

Cumulative Frequency of Baseline MADRS Total Score: 217-PPD-201B - ITT population (Moderate Baseline MADRS Severity Subgroup)

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	Placebo (N=26)	Zuranolone (N =36)	Total (N =62)
Baseline MARDS Total Score, n (%)			
<= 26	0	1 (2.8)	1 (1.6)
<= 27	1 (3.8)	3 (8.3)	4 (6.5)
<= 28	2 (7.7)	7 (19.4)	9 (14.5)
<= 29	4 (15.4)	11 (30.6)	15 (24.2)
<= 30	10 (38.5)	14 (38.9)	24 (38.7)
<= 31	11 (42.3)	20 (55.6)	31 (50.0)
<= 32	17 (65.4)	24 (66.7)	41 (66.1)
<= 33	21 (80.8)	30 (83.3)	51 (82.3)
<= 34	26 (100)	36 (100)	62 (100)

Source: biib125/v_a/germany_amnog/t-bl-madrs-mod.sas:t-bl-madrs-mod-201-itta.rtf **Run Date:** 22OCT2025

2 SF-36

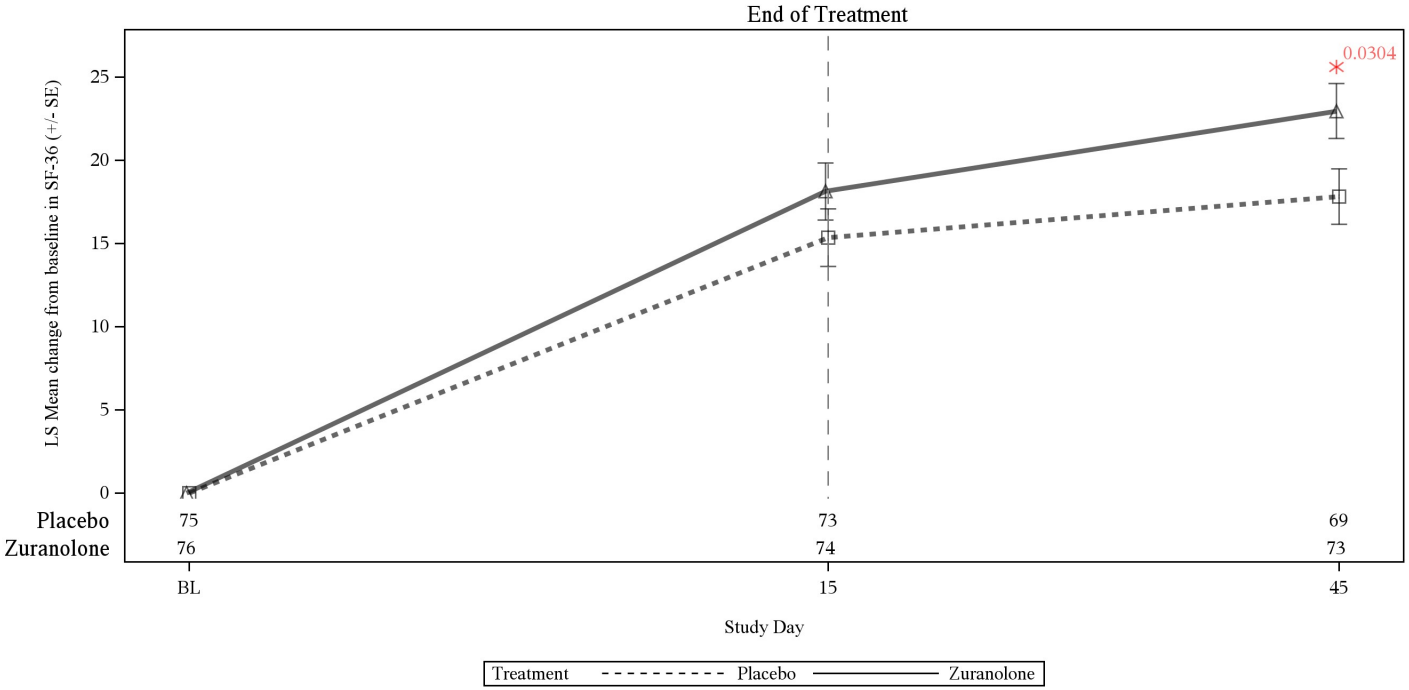
2.1 MCS

2.1.1 MMRM

2.1.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-ovr.sas:f-sf36-ment-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	15.34 (1.728)	18.14 (1.713)
95% CI for the LS Mean	11.93, 18.76	14.75, 21.52
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.79 (2.435)
95% CI for the LS Mean		-2.02, 7.61
p-value		0.2532
Hedges' g (Zuranolone vs. Placebo)		0.188
95% CI for Hedges' g		-0.1358, 0.5123
Day 45		
n	69	73
LS Mean (SE)	17.82 (1.681)	22.96 (1.642)
95% CI for the LS Mean	14.49, 21.14	19.71, 26.20
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.14 (2.351)
95% CI for the LS Mean		0.50, 9.79
p-value		0.0304
Hedges' g (Zuranolone vs. Placebo)		0.365
95% CI for Hedges' g		0.0335, 0.6971

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-ovr.sas:t-sf36-ment-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.1.1.2 Subgruppen

2.1.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.5743
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.7182
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.9945
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.3325
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-int.sas:t-sf36-ment-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.4805(a)
25-29.9	20	21	0.5088(b)
>=30	34	42	0.8924(c)
Onset of PPD			
3rd Trimester	32	32	0.3835
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.2972
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.9228
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-int.sas:t-sf36-ment-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

2.1.1.2 .2 Subgruppenanalysen

2.1.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	13.49 (2.899)	17.85 (3.517)
95% CI for the LS Mean	7.62, 19.36	10.73, 24.97
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.36 (4.561)
95% CI for the LS Mean		-4.87, 13.59
p-value		0.3453
Hedges' g (Zuranolone vs. Placebo)		0.295
95% CI for Hedges' g		-0.3246, 0.9141
Day 45		
n	25	16
LS Mean (SE)	14.10 (3.003)	20.94 (3.721)
95% CI for the LS Mean	8.01, 20.18	13.40, 28.47
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.84 (4.785)
95% CI for the LS Mean		-2.85, 16.53
p-value		0.1613
Hedges' g (Zuranolone vs. Placebo)		0.449
95% CI for Hedges' g		-0.1863, 1.0836

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	16.13 (2.164)	18.40 (1.981)
95% CI for the LS Mean	11.84, 20.43	14.47, 22.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.27 (2.938)
95% CI for the LS Mean		-3.56, 8.09
p-value		0.4423
Hedges' g (Zuranolone vs. Placebo)		0.150
95% CI for Hedges' g		-0.2345, 0.5345
Day 45		
n	44	57
LS Mean (SE)	19.67 (2.072)	23.68 (1.838)
95% CI for the LS Mean	15.56, 23.78	20.04, 27.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.01 (2.775)
95% CI for the LS Mean		-1.49, 9.52
p-value		0.1512
Hedges' g (Zuranolone vs. Placebo)		0.288
95% CI for Hedges' g		-0.1073, 0.6833

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.1.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	17.60 (3.453)	19.02 (3.037)
95% CI for the LS Mean	10.65, 24.55	12.91, 25.13
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.42 (4.600)
95% CI for the LS Mean		-7.84, 10.68
p-value		0.7590
Hedges' g (Zuranolone vs. Placebo)		0.087
95% CI for Hedges' g		-0.4721, 0.6452
Day 45		
n	22	28
LS Mean (SE)	19.99 (3.126)	24.17 (2.750)
95% CI for the LS Mean	13.70, 26.28	18.64, 29.71
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.18 (4.166)
95% CI for the LS Mean		-4.20, 12.57
p-value		0.3207
Hedges' g (Zuranolone vs. Placebo)		0.281
95% CI for Hedges' g		-0.2796, 0.8426

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	14.34 (1.974)	17.50 (2.080)
95% CI for the LS Mean	10.42, 18.26	13.37, 21.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.16 (2.870)
95% CI for the LS Mean		-2.54, 8.86
p-value		0.2744
Hedges' g (Zuranolone vs. Placebo)		0.222
95% CI for Hedges' g		-0.1779, 0.6216
Day 45		
n	47	45
LS Mean (SE)	16.79 (2.027)	22.21 (2.085)
95% CI for the LS Mean	12.77, 20.82	18.06, 26.35
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.41 (2.911)
95% CI for the LS Mean		-0.37, 11.20
p-value		0.0662
Hedges' g (Zuranolone vs. Placebo)		0.385
95% CI for Hedges' g		-0.0279, 0.7971

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.1.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	14.14 (2.792)	18.39 (2.792)
95% CI for the LS Mean	8.55, 19.73	12.80, 23.98
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.25 (3.951)
95% CI for the LS Mean		-3.66, 12.16
p-value		0.2865
Hedges' g (Zuranolone vs. Placebo)		0.270
95% CI for Hedges' g		-0.2303, 0.7699
Day 45		
n	30	30
LS Mean (SE)	17.42 (2.670)	21.75 (2.670)
95% CI for the LS Mean	12.07, 22.77	16.40, 27.10
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.33 (3.778)
95% CI for the LS Mean		-3.24, 11.89
p-value		0.2568
Hedges' g (Zuranolone vs. Placebo)		0.292
95% CI for Hedges' g		-0.2168, 0.8007

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	16.00 (2.324)	18.12 (2.228)
95% CI for the LS Mean	11.38, 20.63	13.68, 22.55
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.11 (3.225)
95% CI for the LS Mean		-4.31, 8.53
p-value		0.5148
Hedges' g (Zuranolone vs. Placebo)		0.144
95% CI for Hedges' g		-0.2923, 0.5806
Day 45		
n	36	42
LS Mean (SE)	18.23 (2.267)	23.97 (2.123)
95% CI for the LS Mean	13.72, 22.74	19.74, 28.20
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.74 (3.112)
95% CI for the LS Mean		-0.46, 11.93
p-value		0.0691
Hedges' g (Zuranolone vs. Placebo)		0.415
95% CI for Hedges' g		-0.0354, 0.8644

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.1.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	12.70 (4.277)	22.61 (3.962)
95% CI for the LS Mean	3.90, 21.50	14.46, 30.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.91 (5.905)
95% CI for the LS Mean		-2.24, 22.06
p-value		0.1055
Hedges' g (Zuranolone vs. Placebo)		0.617
95% CI for Hedges' g		-0.1427, 1.3775
Day 45		
n	11	15
LS Mean (SE)	18.14 (4.443)	24.22 (3.920)
95% CI for the LS Mean	8.99, 27.29	16.11, 32.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.08 (5.996)
95% CI for the LS Mean		-6.29, 18.45
p-value		0.3206
Hedges' g (Zuranolone vs. Placebo)		0.390
95% CI for Hedges' g		-0.3954, 1.1750

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	15.91 (1.896)	17.03 (1.908)
95% CI for the LS Mean	12.16, 19.67	13.25, 20.81
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.12 (2.690)
95% CI for the LS Mean		-4.21, 6.44
p-value		0.6788
Hedges' g (Zuranolone vs. Placebo)		0.076
95% CI for Hedges' g		-0.2839, 0.4351
Day 45		
n	58	58
LS Mean (SE)	17.85 (1.830)	22.68 (1.830)
95% CI for the LS Mean	14.22, 21.47	19.06, 26.31
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.84 (2.587)
95% CI for the LS Mean		-0.29, 9.96
p-value		0.0640
Hedges' g (Zuranolone vs. Placebo)		0.345
95% CI for Hedges' g		-0.0217, 0.7116

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.1.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	15.73 (3.432)	20.18 (4.262)
95% CI for the LS Mean	8.71, 22.74	11.46, 28.89
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.45 (5.479)
95% CI for the LS Mean		-6.75, 15.65
p-value		0.4235
Hedges' g (Zuranolone vs. Placebo)		0.282
95% CI for Hedges' g		-0.4195, 0.9837
Day 45		
n	18	12
LS Mean (SE)	16.18 (3.505)	26.07 (4.308)
95% CI for the LS Mean	9.00, 23.36	17.23, 34.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.89 (5.559)
95% CI for the LS Mean		-1.51, 21.28
p-value		0.0863
Hedges' g (Zuranolone vs. Placebo)		0.645
95% CI for Hedges' g		-0.1035, 1.3934

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	16.03 (3.762)	17.70 (3.725)
95% CI for the LS Mean	8.40, 23.67	10.14, 25.25
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.66 (5.300)
95% CI for the LS Mean		-9.09, 12.41
p-value		0.7557
Hedges' g (Zuranolone vs. Placebo)		0.097
95% CI for Hedges' g		-0.5230, 0.7173
Day 45		
n	20	20
LS Mean (SE)	20.19 (3.368)	24.16 (3.335)
95% CI for the LS Mean	13.37, 27.02	17.41, 30.92
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.97 (4.746)
95% CI for the LS Mean		-5.65, 13.58
p-value		0.4084
Hedges' g (Zuranolone vs. Placebo)		0.259
95% CI for Hedges' g		-0.3632, 0.8816

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	14.89 (2.443)	17.49 (2.190)
95% CI for the LS Mean	10.02, 19.76	13.13, 21.86
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.60 (3.284)
95% CI for the LS Mean		-3.95, 9.15
p-value		0.4312
Hedges' g (Zuranolone vs. Placebo)		0.183
95% CI for Hedges' g		-0.2761, 0.6425
Day 45		
n	31	41
LS Mean (SE)	17.37 (2.416)	21.33 (2.116)
95% CI for the LS Mean	12.55, 22.18	17.11, 25.55
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.96 (3.214)
95% CI for the LS Mean		-2.45, 10.37
p-value		0.2219
Hedges' g (Zuranolone vs. Placebo)		0.290
95% CI for Hedges' g		-0.1787, 0.7591

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.1.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	13.51 (2.723)	17.85 (2.679)
95% CI for the LS Mean	8.06, 18.96	12.49, 23.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.34 (3.828)
95% CI for the LS Mean		-3.32, 12.00
p-value		0.2613
Hedges' g (Zuranolone vs. Placebo)		0.282
95% CI for Hedges' g		-0.2141, 0.7787
Day 45		
n	29	30
LS Mean (SE)	17.16 (2.703)	24.00 (2.658)
95% CI for the LS Mean	11.74, 22.57	18.68, 29.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.85 (3.800)
95% CI for the LS Mean		-0.76, 14.46
p-value		0.0768
Hedges' g (Zuranolone vs. Placebo)		0.463
95% CI for Hedges' g		-0.0540, 0.9804

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	16.89 (2.154)	18.18 (2.147)
95% CI for the LS Mean	12.61, 21.18	13.90, 22.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.28 (3.045)
95% CI for the LS Mean		-4.78, 7.34
p-value		0.6747
Hedges' g (Zuranolone vs. Placebo)		0.091
95% CI for Hedges' g		-0.3368, 0.5190
Day 45		
n	40	43
LS Mean (SE)	18.56 (2.160)	22.01 (2.098)
95% CI for the LS Mean	14.26, 22.86	17.83, 26.18
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.45 (3.015)
95% CI for the LS Mean		-2.55, 9.45
p-value		0.2561
Hedges' g (Zuranolone vs. Placebo)		0.249
95% CI for Hedges' g		-0.1833, 0.6811

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.1.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	14.58 (3.797)	15.25 (3.784)
95% CI for the LS Mean	6.61, 22.55	7.31, 23.20
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.68 (5.577)
95% CI for the LS Mean		-11.00, 12.35
p-value		0.9049
Hedges' g (Zuranolone vs. Placebo)		0.052
95% CI for Hedges' g		-0.8248, 0.9285
Day 45		
n	9	10
LS Mean (SE)	20.89 (3.267)	15.86 (3.100)
95% CI for the LS Mean	13.98, 27.81	9.27, 22.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-5.03 (4.773)
95% CI for the LS Mean		-15.14, 5.08
p-value		0.3072
Hedges' g (Zuranolone vs. Placebo)		-0.463
95% CI for Hedges' g		-1.3752, 0.4497

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	15.50 (1.925)	18.50 (1.905)
95% CI for the LS Mean	11.69, 19.31	14.73, 22.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.00 (2.708)
95% CI for the LS Mean		-2.36, 8.37
p-value		0.2696
Hedges' g (Zuranolone vs. Placebo)		0.196
95% CI for Hedges' g		-0.1530, 0.5443
Day 45		
n	60	63
LS Mean (SE)	17.38 (1.875)	23.99 (1.835)
95% CI for the LS Mean	13.67, 21.09	20.36, 27.62
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.61 (2.624)
95% CI for the LS Mean		1.42, 11.81
p-value		0.0130
Hedges' g (Zuranolone vs. Placebo)		0.452
95% CI for Hedges' g		0.0936, 0.8097

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.1.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	16.00 (1.934)	18.55 (1.852)
95% CI for the LS Mean	12.17, 19.83	14.89, 22.22
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.55 (2.678)
95% CI for the LS Mean		-2.75, 7.86
p-value		0.3422
Hedges' g (Zuranolone vs. Placebo)		0.171
95% CI for Hedges' g		-0.1833, 0.5254
Day 45		
n	55	64
LS Mean (SE)	18.06 (1.916)	23.10 (1.791)
95% CI for the LS Mean	14.27, 21.86	19.56, 26.65
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.04 (2.623)
95% CI for the LS Mean		-0.15, 10.24
p-value		0.0571
Hedges' g (Zuranolone vs. Placebo)		0.351
95% CI for Hedges' g		-0.0121, 0.7142

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	12.69 (4.073)	15.35 (4.824)
95% CI for the LS Mean	4.22, 21.16	5.32, 25.38
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.66 (6.478)
95% CI for the LS Mean		-10.80, 16.11
p-value		0.6859
Hedges' g (Zuranolone vs. Placebo)		0.164
95% CI for Hedges' g		-0.6490, 0.9767
Day 45		
n	14	9
LS Mean (SE)	16.81 (3.746)	22.04 (4.691)
95% CI for the LS Mean	8.98, 24.64	12.30, 31.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.22 (6.221)
95% CI for the LS Mean		-7.69, 18.14
p-value		0.4102
Hedges' g (Zuranolone vs. Placebo)		0.346
95% CI for Hedges' g		-0.4974, 1.1892

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

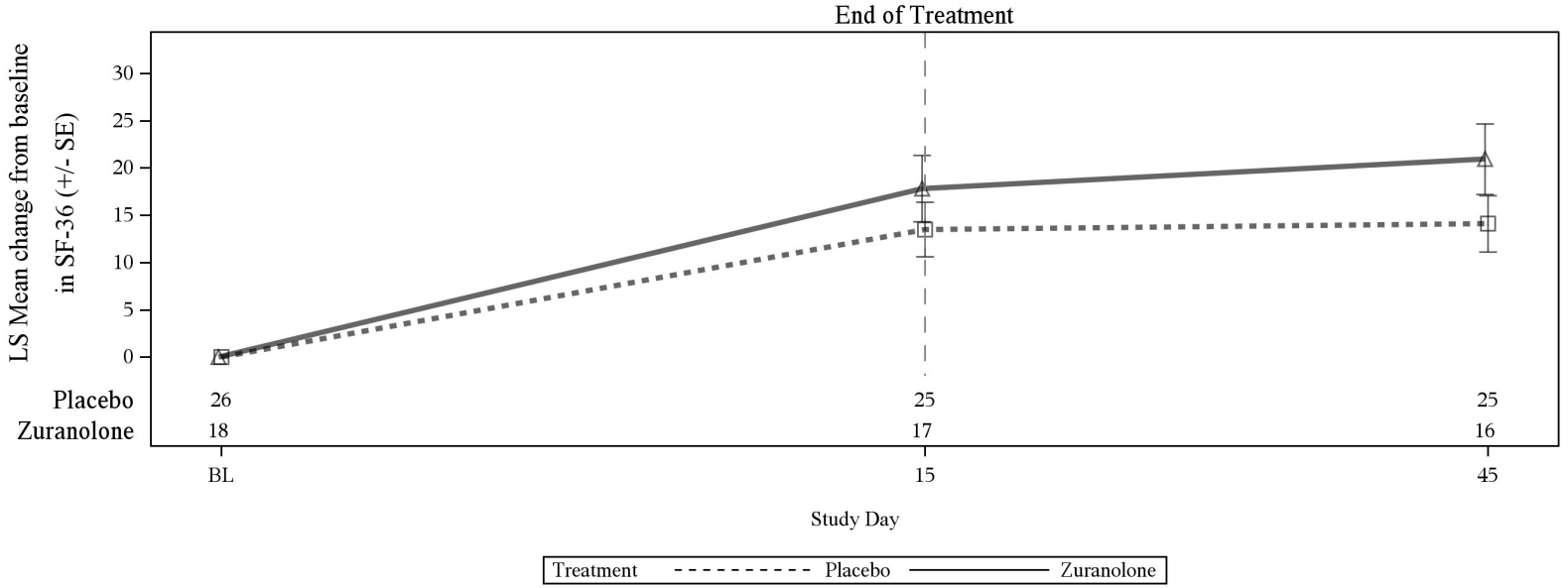
Source: biib125/v_a/germany_amnog/t-sf36-ment-mmrm-201-by.sas:t-sf36-ment-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.1.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

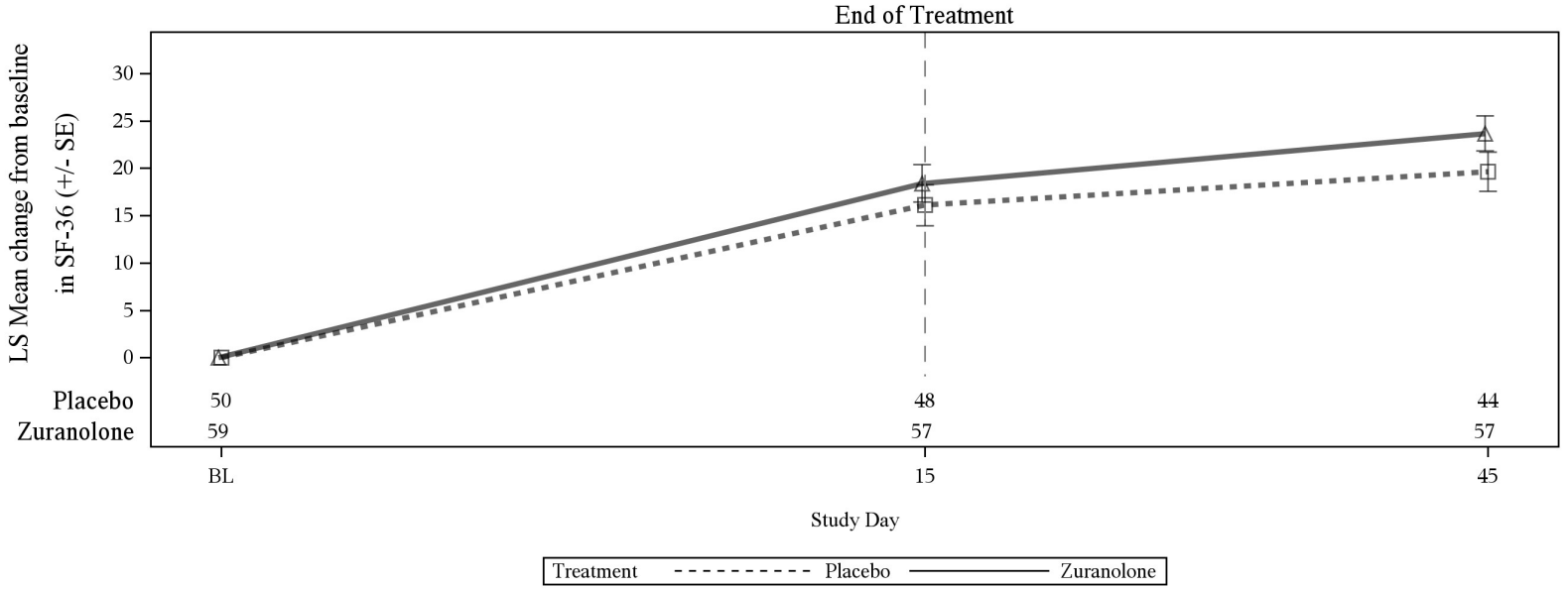
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Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

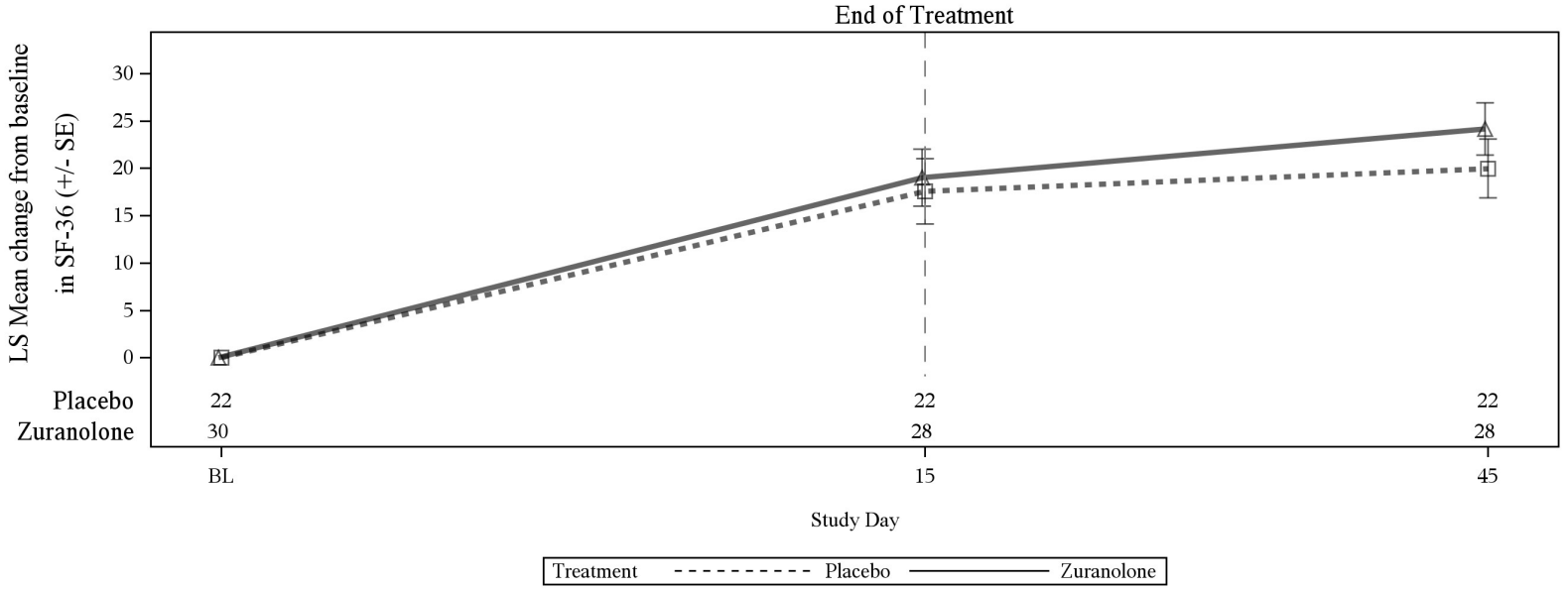
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Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

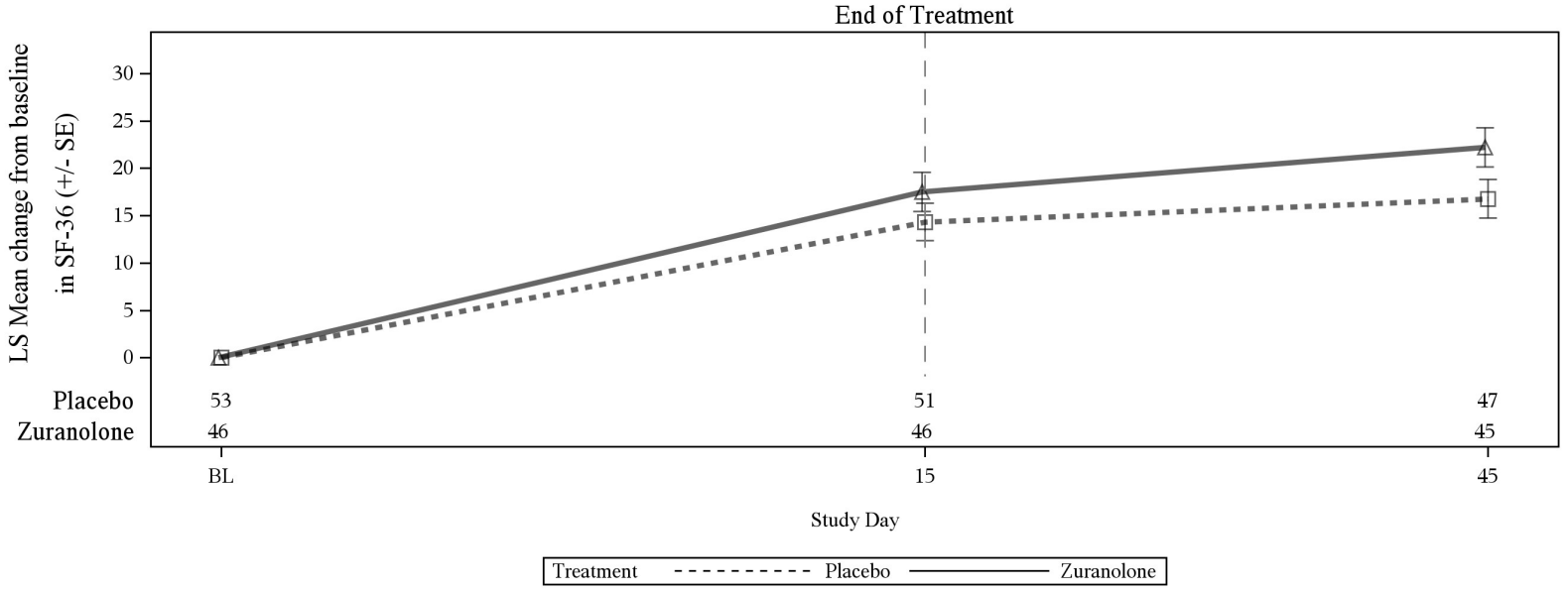
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

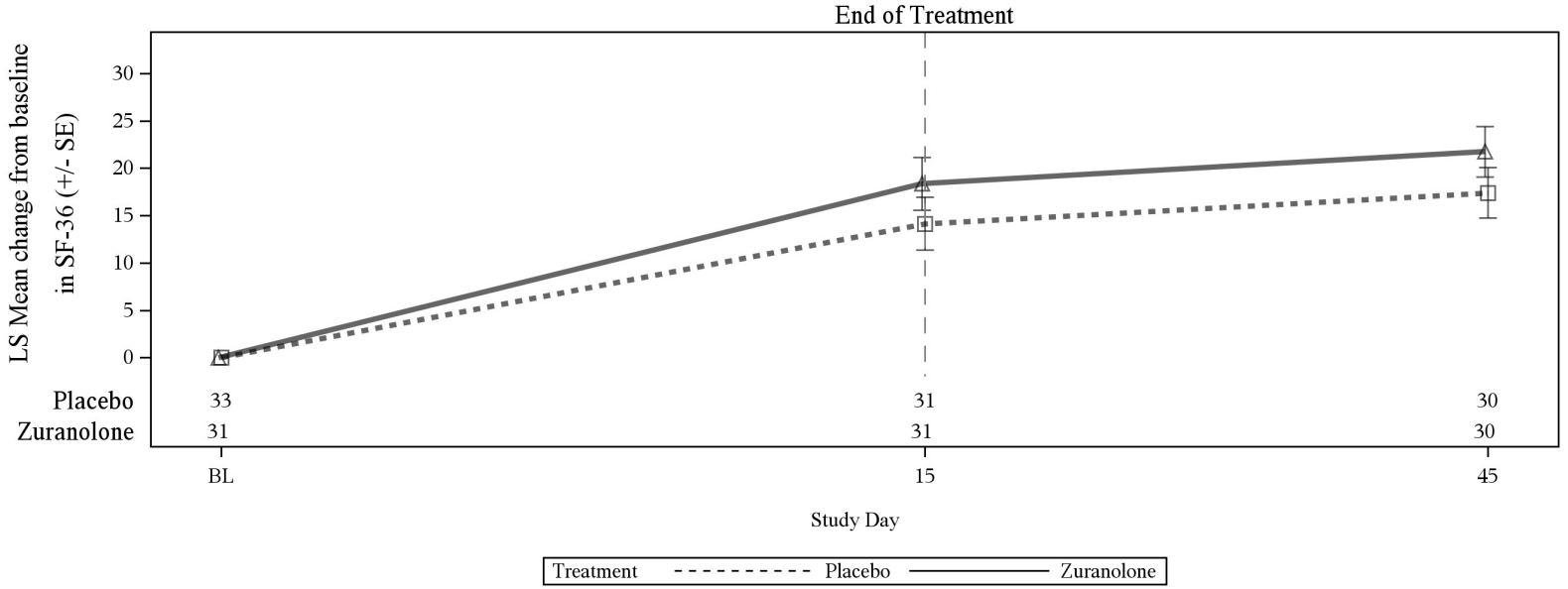
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

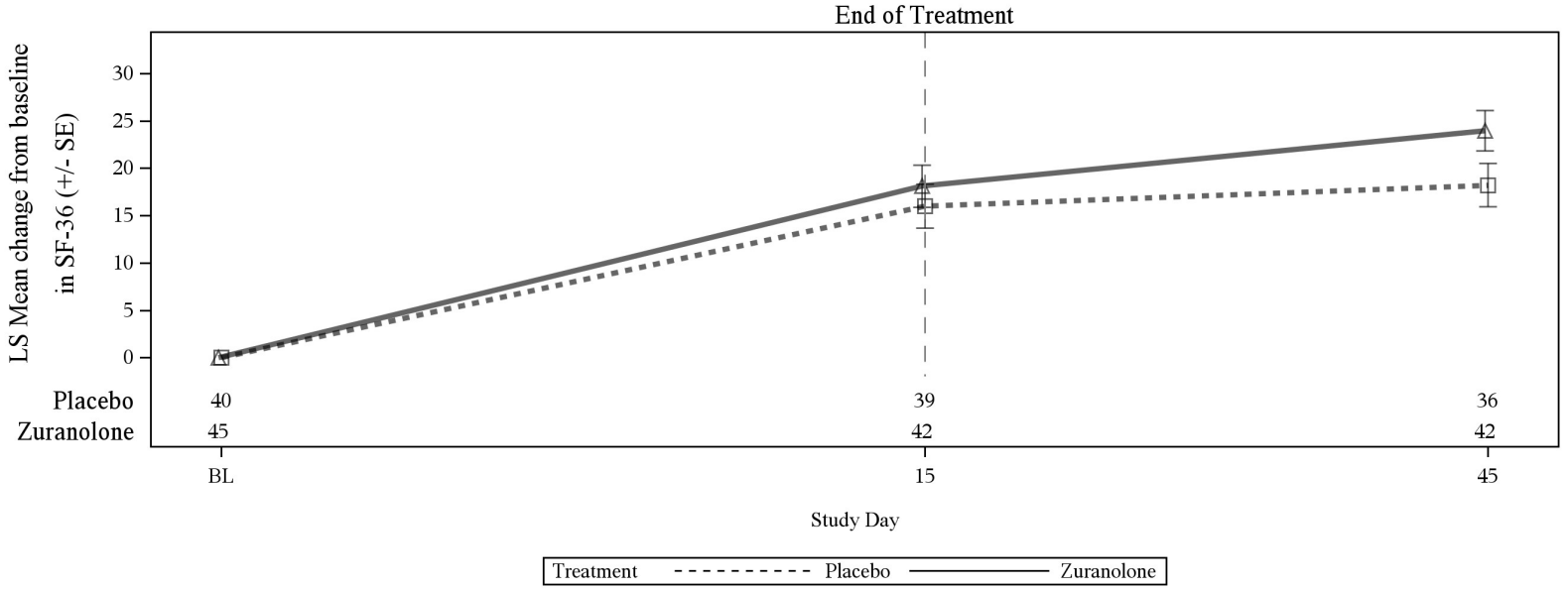
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Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

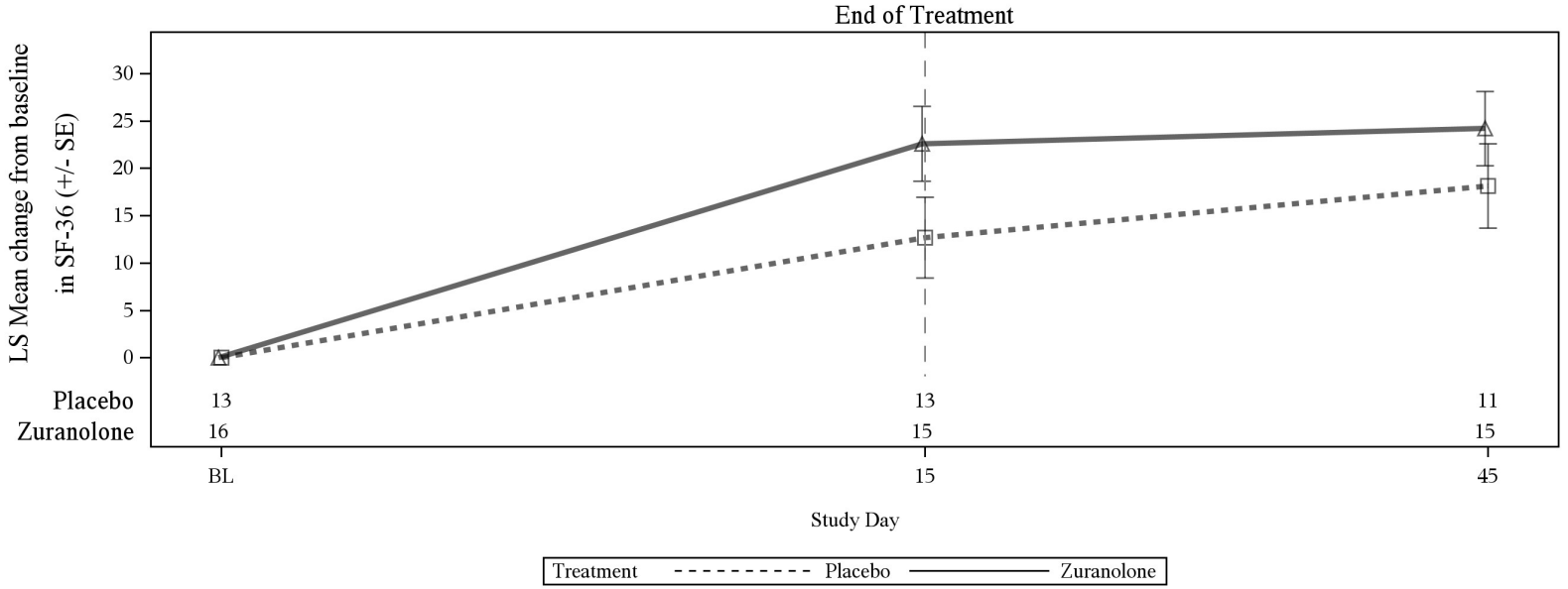
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 7 of 17

Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

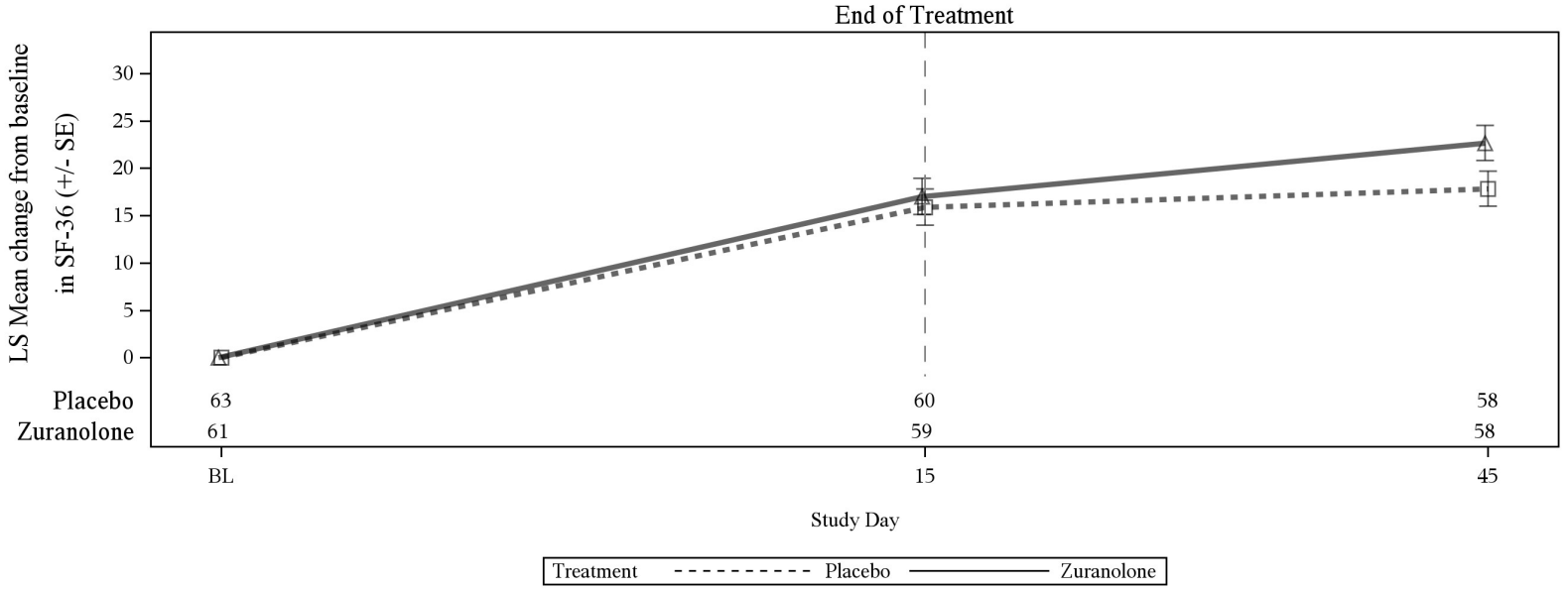
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

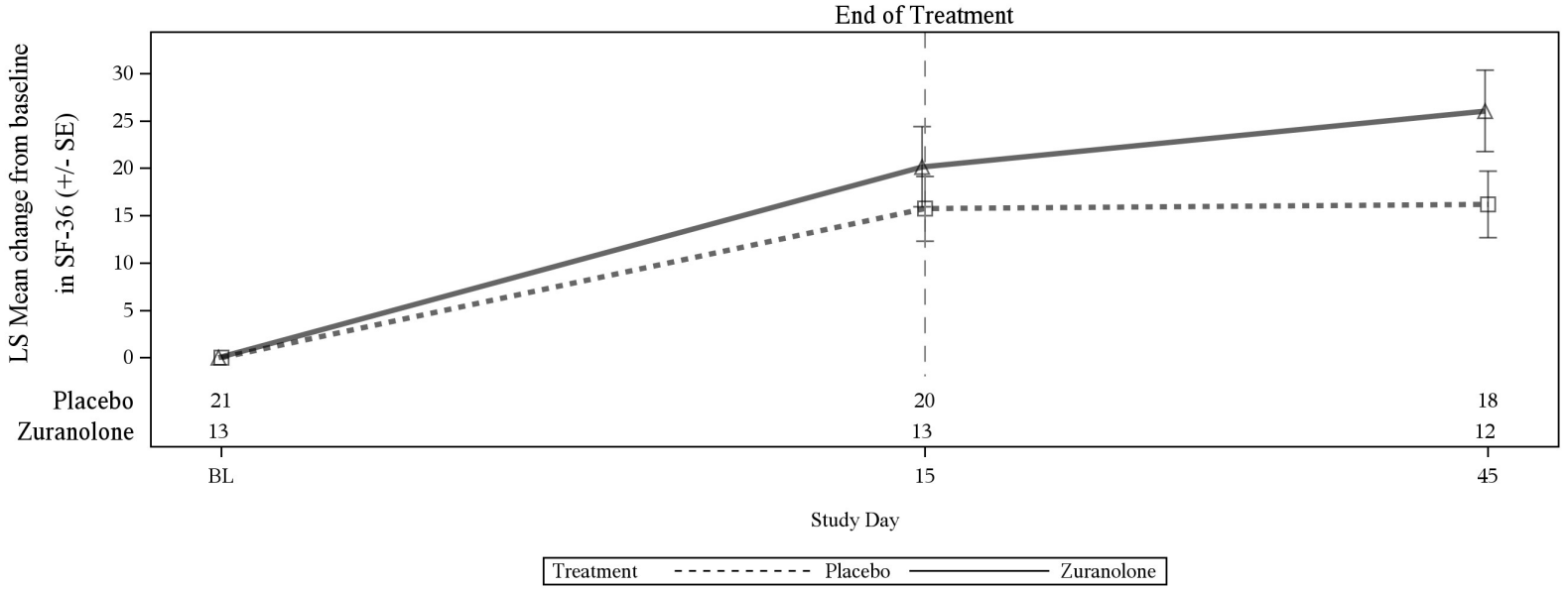
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

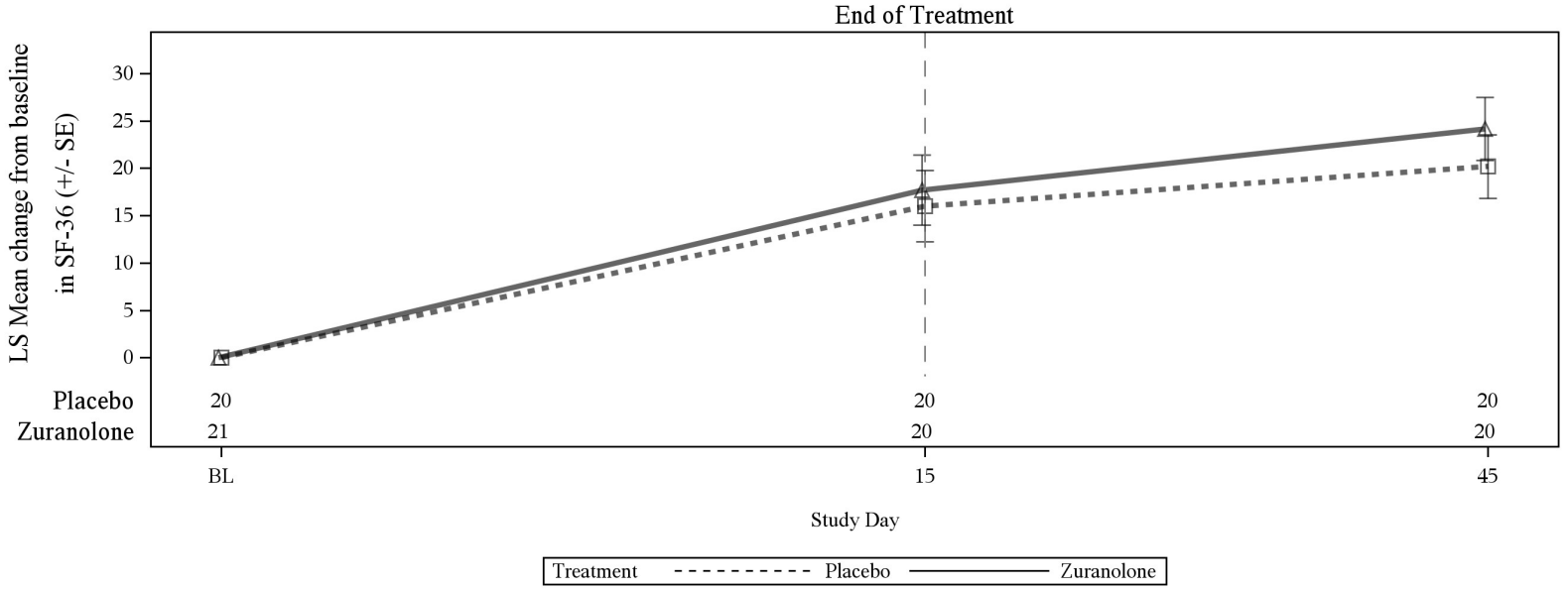
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

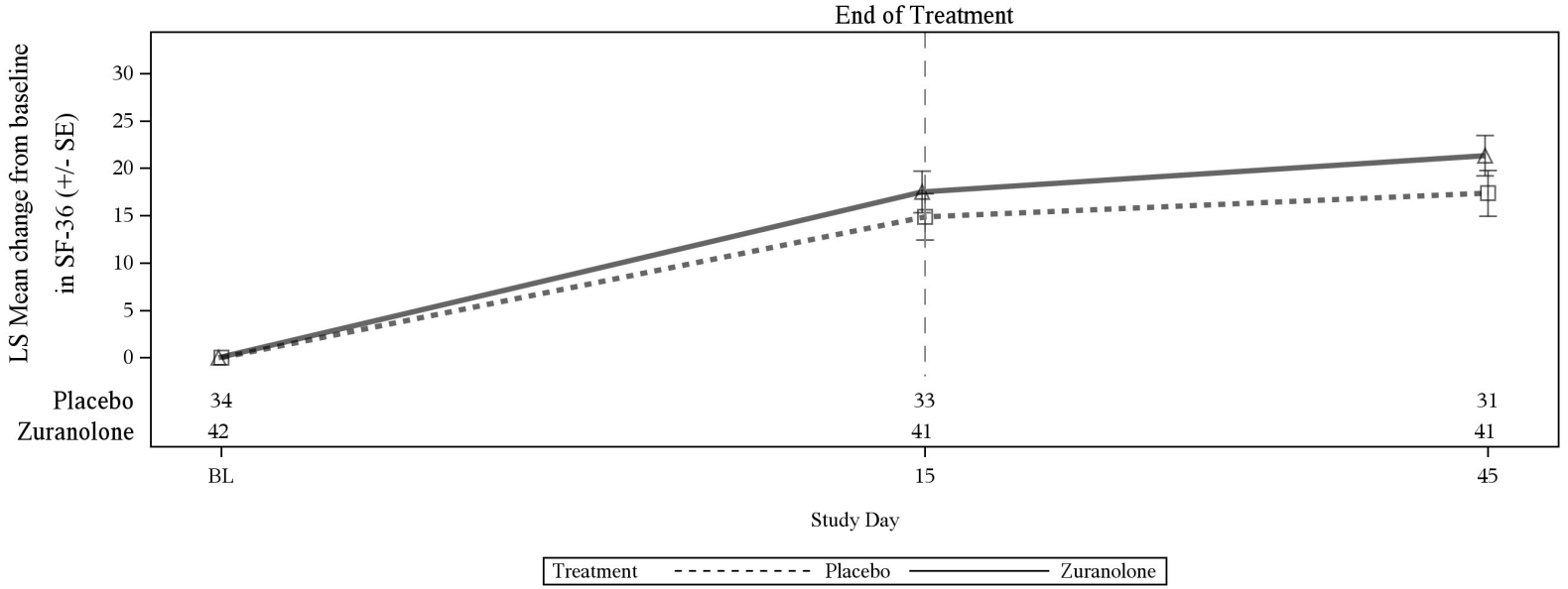
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

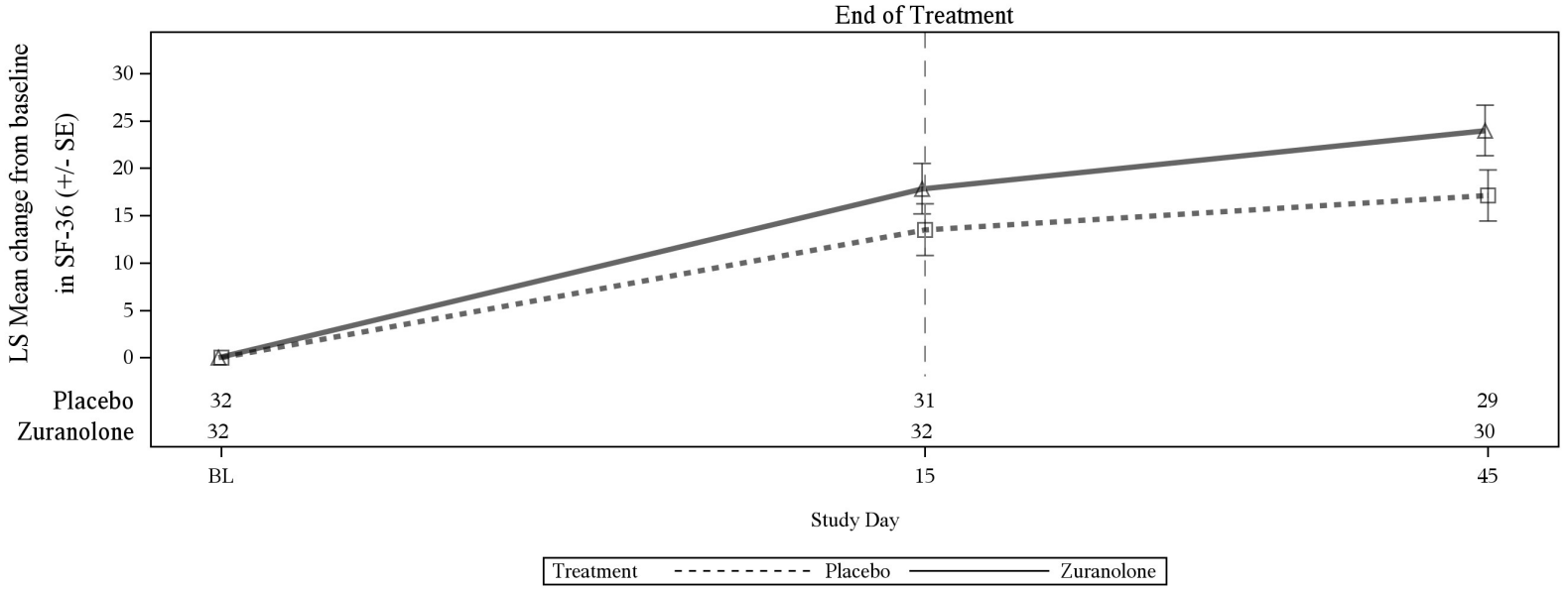
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

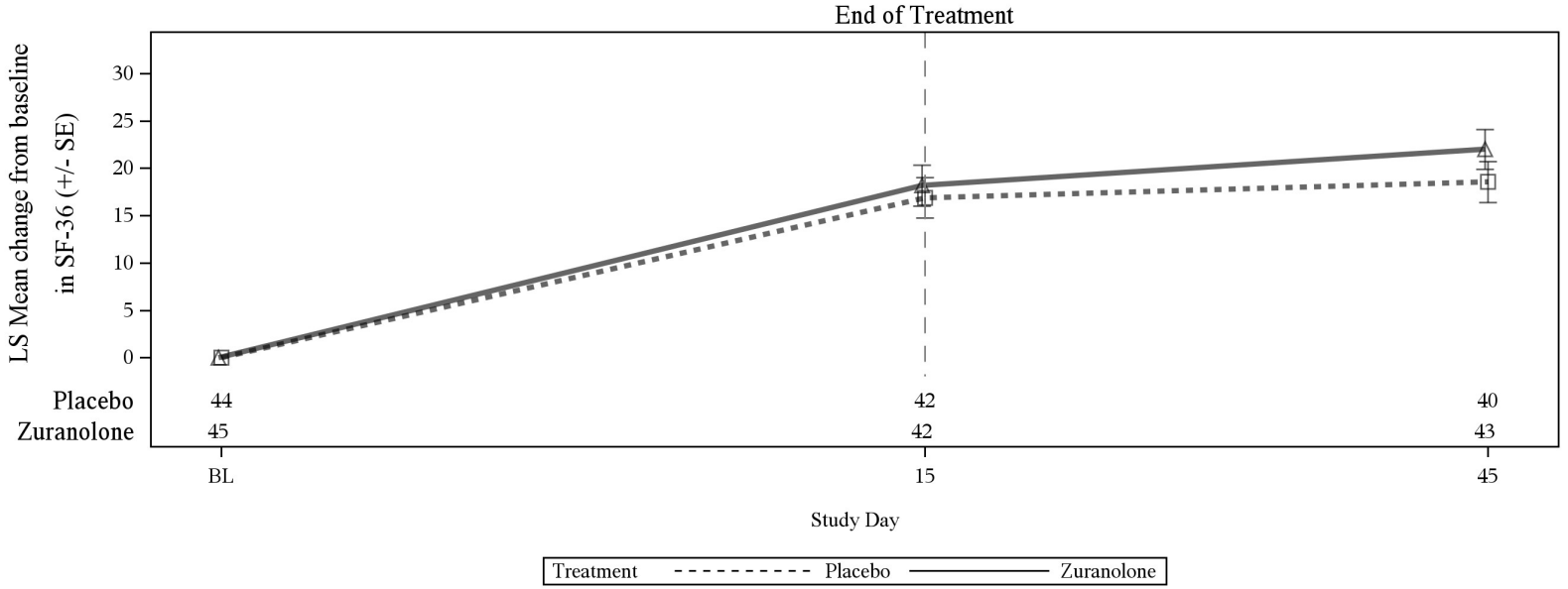
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

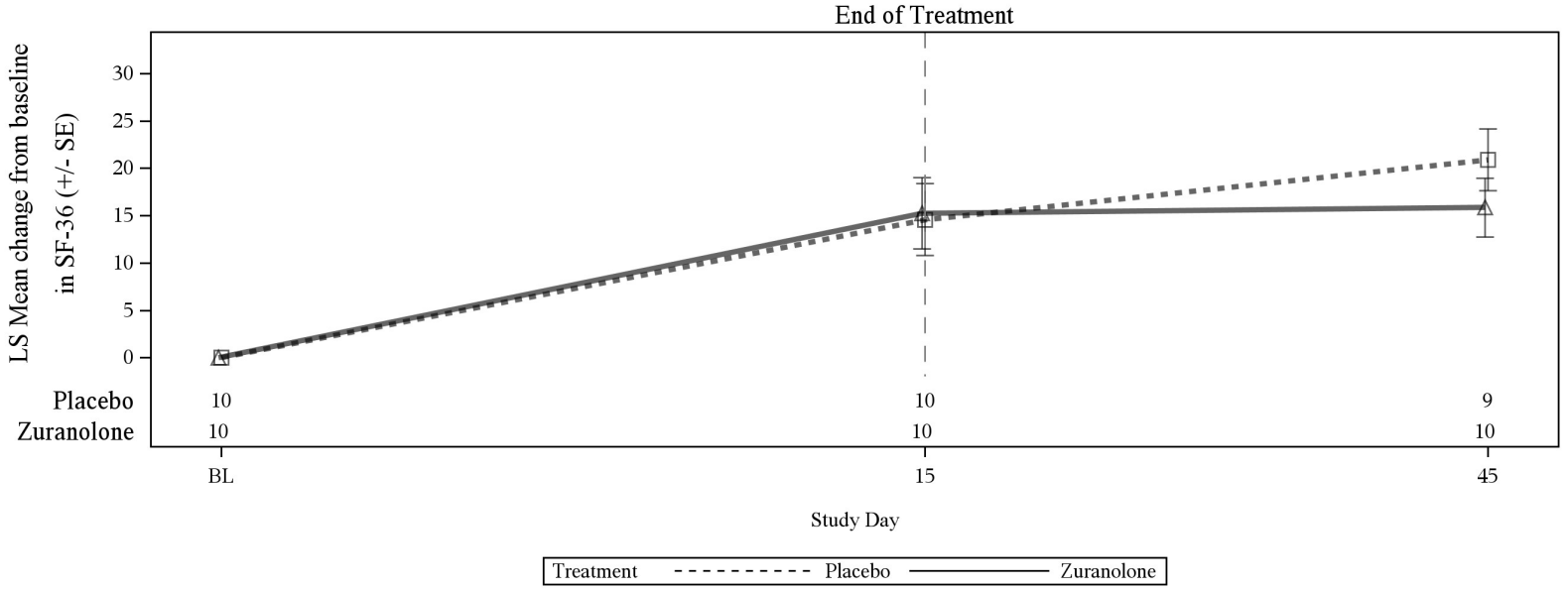
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

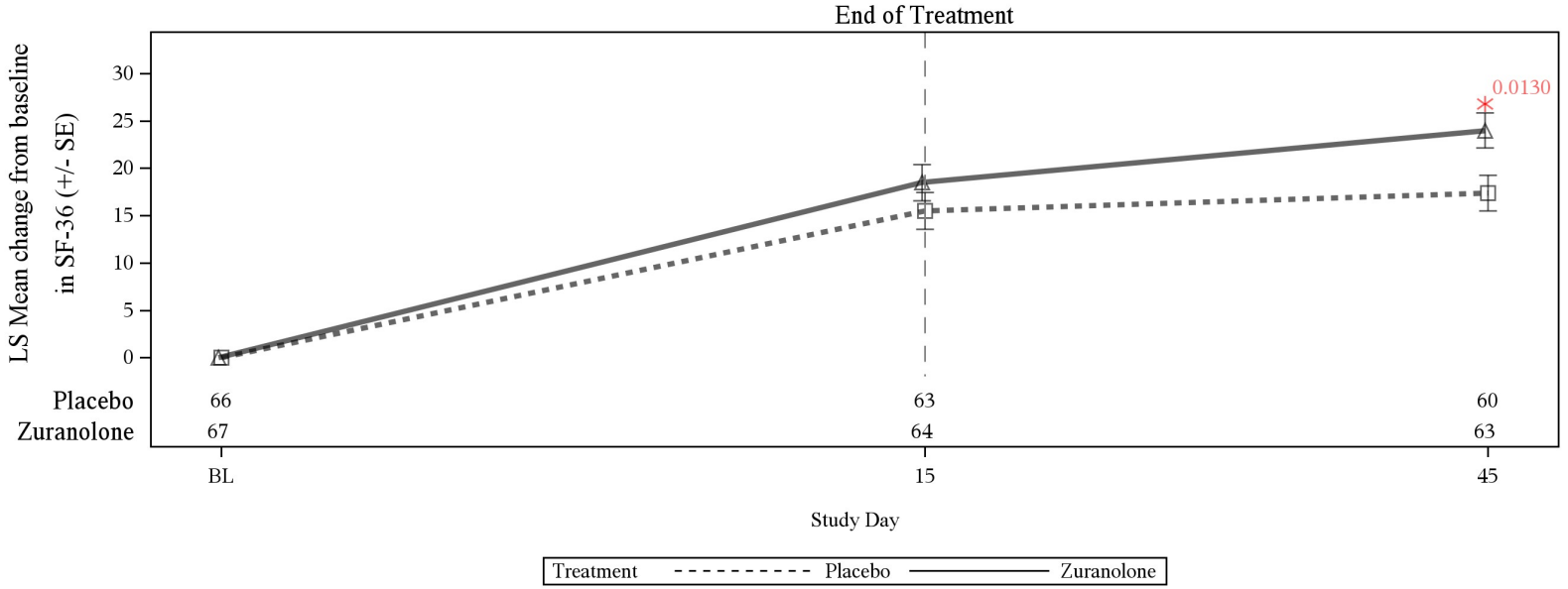
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

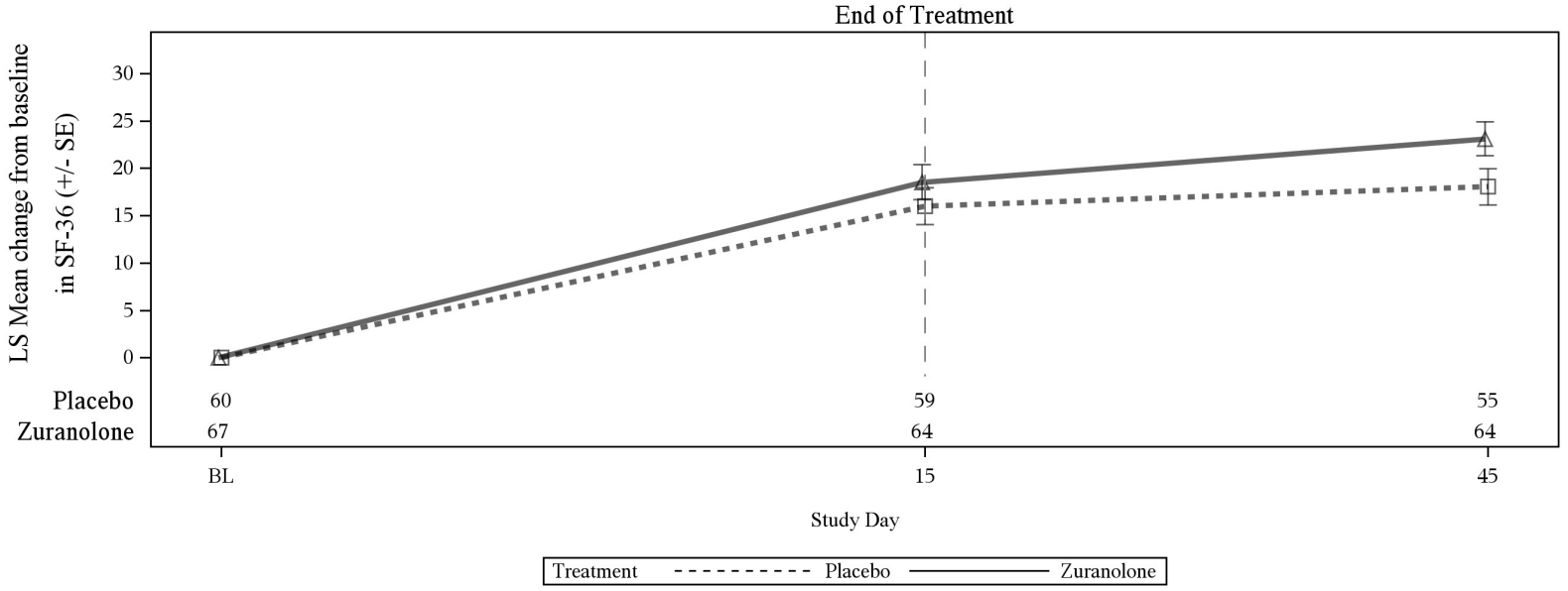
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

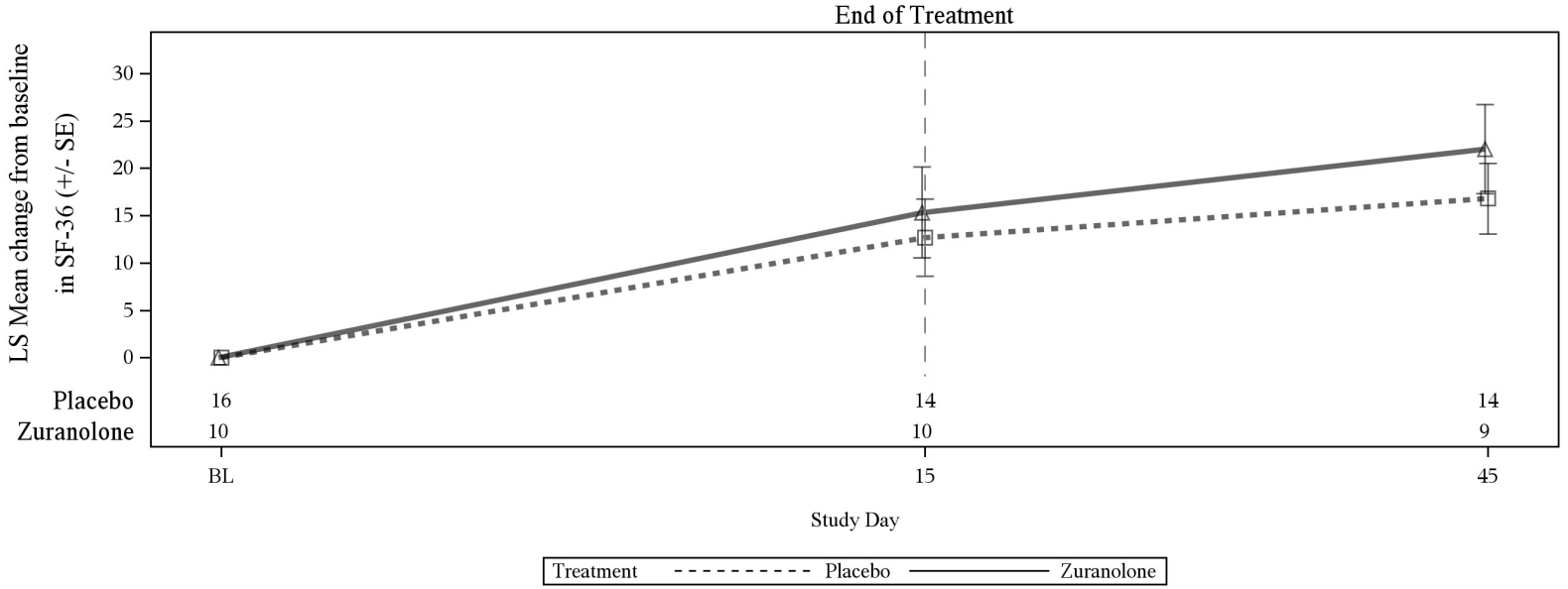
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Component Summary by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Mental Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-ment-mmrm-201-by.sas:f-sf36-ment-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

2.1.2 Ansprechen

2.1.2.1 Responder-Analysen

2.1.2.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with a response, n (%) [2]	47 (62.7)	50 (65.8)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.058
95% CI for the RR		(0.835, 1.341)
p-value for RR		0.6393
OR - Odds Ratio (Zuranolone vs. Placebo)		1.176
95% CI for the OR		(0.599, 2.307)
p-value for OR		0.6376
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.042
95% CI for the ARR		(-0.110, 0.195)
p-value for ARR		0.5843

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-ovr.sas:t-sf36-ment-resp15-201-ovr-itta.rtf **Run Date:** 25SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	48 (64.0)	59 (77.6)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.223
95% CI for the RR		(0.995, 1.502)
p-value for RR		0.0555
OR - Odds Ratio (Zuranolone vs. Placebo)		2.028
95% CI for the OR		(0.993, 4.144)
p-value for OR		0.0525
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.158
95% CI for the ARR		(0.019, 0.297)
p-value for ARR		0.0260

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-ovr.sas:t-sf36-ment-resp15-201-ovr-itta.rtf **Run Date:** 25SEP2025

2.1.2.1 .2 Subgruppen

2.1.2.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	47 (62.7)	50 (65.8)	
Number of subjects with response at Day 45, n (%)	48 (64.0)	59 (77.6)	
Age Group (years)			0.6564
Day 15			
18 - 24, n / N (%)	14/25 (56.0)	11/17 (64.7)	
25 - 45, n / N (%)	33/50 (66.0)	39/59 (66.1)	
Day 45			
18 - 24, n / N (%)	15/25 (60.0)	13/17 (76.5)	
25 - 45, n / N (%)	33/50 (66.0)	46/59 (78.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-int.sas:t-sf36-ment-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.0827
Day 15			
<28, n / N (%)	16/22 (72.7)	18/30 (60.0)	
>=28, n / N (%)	31/53 (58.5)	32/46 (69.6)	
Day 45			
<28, n / N (%)	17/22 (77.3)	23/30 (76.7)	
>=28, n / N (%)	31/53 (58.5)	36/46 (78.3)	
Race Group (Black or African American, White)			0.4123
Day 15			
Black or African American, n / N (%)	17/32 (53.1)	21/31 (67.7)	
White, n / N (%)	28/40 (70.0)	28/44 (63.6)	
Day 45			
Black or African American, n / N (%)	21/32 (65.6)	25/31 (80.6)	
White, n / N (%)	25/40 (62.5)	33/44 (75.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-int.sas:t-sf36-ment-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.1680
Day 15			
Yes, n / N (%)	7/13 (53.8)	12/16 (75.0)	
No, n / N (%)	40/62 (64.5)	38/60 (63.3)	
Day 45			
Yes, n / N (%)	7/13 (53.8)	13/16 (81.3)	
No, n / N (%)	41/62 (66.1)	46/60 (76.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-int.sas:t-sf36-ment-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 4 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.9671(a) 0.5710(b) 0.5664(c)
Day 15			
<=24.9, n / N (%)	15/21 (71.4)	9/13 (69.2)	
25-29.9, n / N (%)	12/20 (60.0)	14/21 (66.7)	
>=30, n / N (%)	20/34 (58.8)	27/42 (64.3)	
Day 45			
<=24.9, n / N (%)	12/21 (57.1)	9/13 (69.2)	
25-29.9, n / N (%)	15/20 (75.0)	16/21 (76.2)	
>=30, n / N (%)	21/34 (61.8)	34/42 (81.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-int.sas:t-sf36-ment-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.1213
Day 15			
3rd Trimester, n / N (%)	17/32 (53.1)	22/32 (68.8)	
Postpartum, n / N (%)	30/43 (69.8)	28/44 (63.6)	
Day 45			
3rd Trimester, n / N (%)	19/32 (59.4)	26/32 (81.3)	
Postpartum, n / N (%)	29/43 (67.4)	33/44 (75.0)	
Family History of PPD			0.7735
Day 15			
Yes, n / N (%)	6/10 (60.0)	5/10 (50.0)	
No/Unknown, n / N (%)	41/65 (63.1)	45/66 (68.2)	
Day 45			
Yes, n / N (%)	7/10 (70.0)	8/10 (80.0)	
No/Unknown, n / N (%)	41/65 (63.1)	51/66 (77.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-int.sas:t-sf36-ment-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.5831
Day 15			
1st Episode, n / N (%)	39/59 (66.1)	44/66 (66.7)	
Recurrent Episode, n / N (%)	8/16 (50.0)	6/10 (60.0)	
Day 45			
1st Episode, n / N (%)	38/59 (64.4)	51/66 (77.3)	
Recurrent Episode, n / N (%)	10/16 (62.5)	8/10 (80.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	6/8 (75.0)	6/10 (60.0)	
>=20, n / N (%)	41/67 (61.2)	44/66 (66.7)	
Day 45			
<20, n / N (%)	5/8 (62.5)	6/10 (60.0)	
>=20, n / N (%)	43/67 (64.2)	53/66 (80.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-int.sas:t-sf36-ment-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

2.1.2.1 .2 .2 Subgruppenanalysen

2.1.2.1 .2 .2 .1 Alter

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 15		
Number of subjects with a response, n (%) [2]	14 (56.0)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.159
95% CI for the RR		(0.711, 1.891)
p-value for RR		0.5538
Day 45		
Number of subjects with a response, n (%) [2]	15 (60.0)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.279
95% CI for the RR		(0.843, 1.939)
p-value for RR		0.2472

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 15		
Number of subjects with a response, n (%) [2]	33 (66.0)	39 (66.1)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.022
95% CI for the RR		(0.782, 1.334)
p-value for RR		0.8750
Day 45		
Number of subjects with a response, n (%) [2]	33 (66.0)	46 (78.0)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.205
95% CI for the RR		(0.951, 1.527)
p-value for RR		0.1229

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.1.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 15		
Number of subjects with a response, n (%) [2]	16 (72.7)	18 (60.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.830
95% CI for the RR		(0.565, 1.219)
p-value for RR		0.3419
Day 45		
Number of subjects with a response, n (%) [2]	17 (77.3)	23 (76.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.998
95% CI for the RR		(0.739, 1.347)
p-value for RR		0.9890

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 15		
Number of subjects with a response, n (%) [2]	31 (58.5)	32 (69.6)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.203
95% CI for the RR		(0.895, 1.616)
p-value for RR		0.2211
Day 45		
Number of subjects with a response, n (%) [2]	31 (58.5)	36 (78.3)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.353
95% CI for the RR		(1.035, 1.768)
p-value for RR		0.0269

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.1.2.1 .2 .2 .3 Abstammung

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 15		
Number of subjects with a response, n (%) [2]	17 (53.1)	21 (67.7)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.272
95% CI for the RR		(0.852, 1.899)
p-value for RR		0.2391
Day 45		
Number of subjects with a response, n (%) [2]	21 (65.6)	25 (80.6)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.226
95% CI for the RR		(0.909, 1.653)
p-value for RR		0.1819

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 15		
Number of subjects with a response, n (%) [2]	28 (70.0)	28 (63.6)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.926
95% CI for the RR		(0.690, 1.243)
p-value for RR		0.6084
Day 45		
Number of subjects with a response, n (%) [2]	25 (62.5)	33 (75.0)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.222
95% CI for the RR		(0.917, 1.629)
p-value for RR		0.1709

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.1.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 15		
Number of subjects with a response, n (%) [2]	7 (53.8)	12 (75.0)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.396
95% CI for the RR		(0.792, 2.459)
p-value for RR		0.2483
Day 45		
Number of subjects with a response, n (%) [2]	7 (53.8)	13 (81.3)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.512
95% CI for the RR		(0.877, 2.606)
p-value for RR		0.1365

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 15		
Number of subjects with a response, n (%) [2]	40 (64.5)	38 (63.3)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.981
95% CI for the RR		(0.753, 1.278)
p-value for RR		0.8852
Day 45		
Number of subjects with a response, n (%) [2]	41 (66.1)	46 (76.7)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.158
95% CI for the RR		(0.928, 1.446)
p-value for RR		0.1947

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.1.2.1 .2 .2 .5 BMI

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 15		
Number of subjects with a response, n (%) [2]	15 (71.4)	9 (69.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.954
95% CI for the RR		(0.597, 1.525)
p-value for RR		0.8448
Day 45		
Number of subjects with a response, n (%) [2]	12 (57.1)	9 (69.2)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.193
95% CI for the RR		(0.709, 2.006)
p-value for RR		0.5061

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 15		
Number of subjects with a response, n (%) [2]	12 (60.0)	14 (66.7)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.124
95% CI for the RR		(0.710, 1.781)
p-value for RR		0.6178
Day 45		
Number of subjects with a response, n (%) [2]	15 (75.0)	16 (76.2)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.028
95% CI for the RR		(0.731, 1.446)
p-value for RR		0.8746

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 15		
Number of subjects with a response, n (%) [2]	20 (58.8)	27 (64.3)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.111
95% CI for the RR		(0.776, 1.592)
p-value for RR		0.5644
Day 45		
Number of subjects with a response, n (%) [2]	21 (61.8)	34 (81.0)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.333
95% CI for the RR		(0.985, 1.804)
p-value for RR		0.0625

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.1.2.1 .2 .2 .6 Beginn der PPD

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 15		
Number of subjects with a response, n (%) [2]	17 (53.1)	22 (68.8)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.300
95% CI for the RR		(0.873, 1.936)
p-value for RR		0.1972
Day 45		
Number of subjects with a response, n (%) [2]	19 (59.4)	26 (81.3)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.374
95% CI for the RR		(0.992, 1.904)
p-value for RR		0.0558

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 15		
Number of subjects with a response, n (%) [2]	30 (69.8)	28 (63.6)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.912
95% CI for the RR		(0.682, 1.221)
p-value for RR		0.5368
Day 45		
Number of subjects with a response, n (%) [2]	29 (67.4)	33 (75.0)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.112
95% CI for the RR		(0.851, 1.454)
p-value for RR		0.4367

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.1.2.1 .2 .2 .7 PPD in der Familie

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 15		
Number of subjects with a response, n (%) [2]	6 (60.0)	5 (50.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.938
95% CI for the RR		(0.434, 2.025)
p-value for RR		0.8695
Day 45		
Number of subjects with a response, n (%) [2]	7 (70.0)	8 (80.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.286
95% CI for the RR		(0.748, 2.209)
p-value for RR		0.3627

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 15		
Number of subjects with a response, n (%) [2]	41 (63.1)	45 (68.2)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.078
95% CI for the RR		(0.841, 1.381)
p-value for RR		0.5557
Day 45		
Number of subjects with a response, n (%) [2]	41 (63.1)	51 (77.3)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.221
95% CI for the RR		(0.974, 1.531)
p-value for RR		0.0834

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.1.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 15		
Number of subjects with a response, n (%) [2]	39 (66.1)	44 (66.7)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.009
95% CI for the RR		(0.786, 1.296)
p-value for RR		0.9423
Day 45		
Number of subjects with a response, n (%) [2]	38 (64.4)	51 (77.3)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.201
95% CI for the RR		(0.956, 1.508)
p-value for RR		0.1159

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 15		
Number of subjects with a response, n (%) [2]	8 (50.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.233
95% CI for the RR		(0.595, 2.559)
p-value for RR		0.5731
Day 45		
Number of subjects with a response, n (%) [2]	10 (62.5)	8 (80.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.316
95% CI for the RR		(0.716, 2.418)
p-value for RR		0.3771

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response (9.6 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

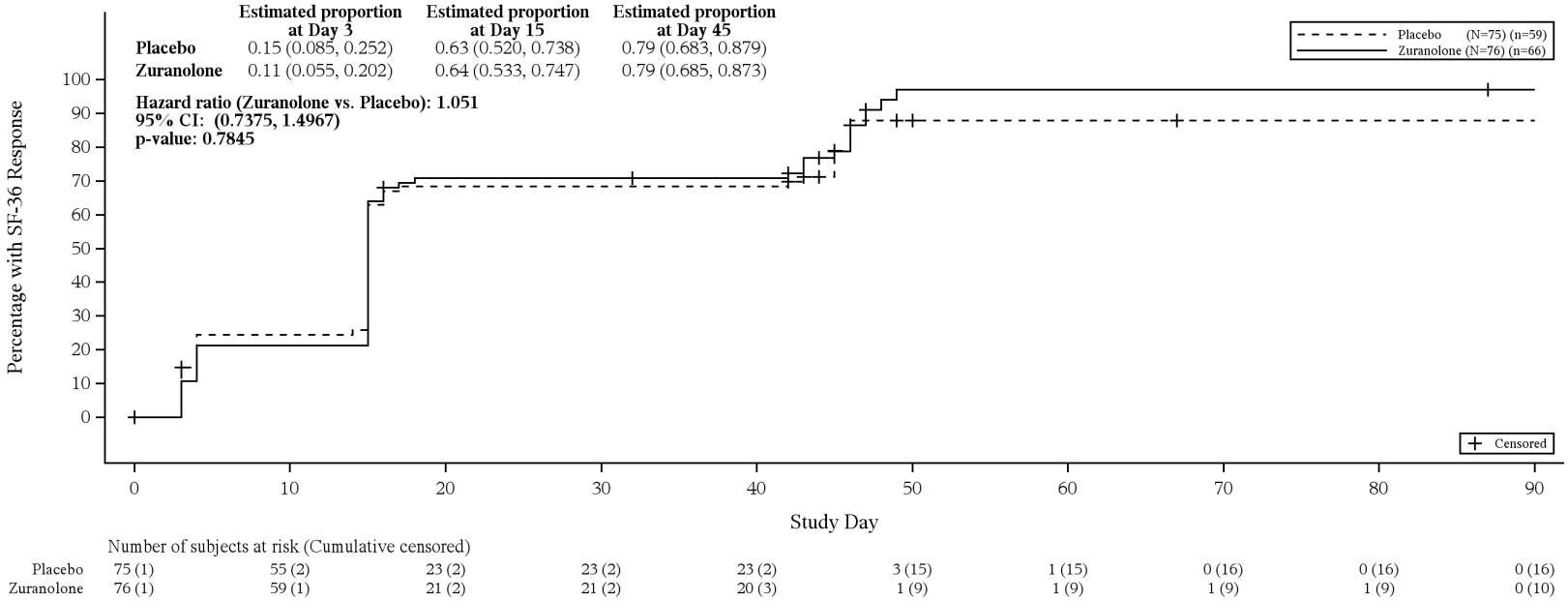
Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-201-by.sas:t-sf36-ment-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.1.2.2 TTE-Analysen

2.1.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-ment-resp15-tte-201-ovr.sas:f-sf36-ment-resp15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	59 (78.7)	66 (86.8)
Time to first SF-36 Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	14.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	45.0 (16.0 , 46.0)	43.0 (16.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.051
95% CI for the HR		(0.7375 , 1.4967)
p-value for the HR		0.7845

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.
Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-ovr.sas:t-sf36-ment-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.1.2.2 .2 Subgruppen

2.1.2.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	59 (78.7)	66 (86.8)	
Age Group (years)			
18 - 24, n / N (%)	19/25 (76.0)	16/17 (94.1)	0.1271
25 - 45, n / N (%)	40/50 (80.0)	50/59 (84.7)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	19/22 (86.4)	25/30 (83.3)	0.6552
>=28, n / N (%)	40/53 (75.5)	41/46 (89.1)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	26/32 (81.3)	29/31 (93.5)	0.8129
White, n / N (%)	31/40 (77.5)	36/44 (81.8)	
Antidepressant Use at Baseline			
Yes, n / N (%)	9/13 (69.2)	14/16 (87.5)	0.0636
No, n / N (%)	50/62 (80.6)	52/60 (86.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-int.sas:t-sf36-ment-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	16/21 (76.2)	12/13 (92.3)	0.8242(a)
25-29.9, n / N (%)	16/20 (80.0)	17/21 (81.0)	0.8935(b)
>=30, n / N (%)	27/34 (79.4)	37/42 (88.1)	0.9031(c)
Onset of PPD			
3rd Trimester, n / N (%)	25/32 (78.1)	30/32 (93.8)	0.2624
Postpartum, n / N (%)	34/43 (79.1)	36/44 (81.8)	
Family History of PPD			
Yes, n / N (%)	9/10 (90.0)	8/10 (80.0)	0.7180
No/Unknown, n / N (%)	50/65 (76.9)	58/66 (87.9)	
History of PPD			
1st Episode, n / N (%)	48/59 (81.4)	57/66 (86.4)	0.7477
Recurrent Episode, n / N (%)	11/16 (68.8)	9/10 (90.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	6/8 (75.0)	7/10 (70.0)	NA
>=20, n / N (%)	53/67 (79.1)	59/66 (89.4)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-int.sas:t-sf36-ment-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.1.2.2 .2 .2 Subgruppenanalysen

2.1.2.2 .2 .2 .1 Alter

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	19 (76.0)	16 (94.1)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 45.0)	15.0 (4.0 , 16.0)
75th percentile - Q3 (95% CI)	46.0 (17.0, NE)	16.0 (15.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.755
95% CI for the HR		(0.8775 , 3.5084)
p-value for the HR		0.1117

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	40 (80.0)	50 (84.7)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	14.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	45.0 (15.0 , 46.0)	46.0 (16.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.886
95% CI for the HR		(0.5805 , 1.3521)
p-value for the HR		0.5746

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.1.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	19 (86.4)	25 (83.3)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (15.0 , 42.0)
75th percentile - Q3 (95% CI)	42.0 (15.0, NE)	45.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.913
95% CI for the HR		(0.5003 , 1.6675)
p-value for the HR		0.7679

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	40 (75.5)	41 (89.1)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 16.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	45.0 (16.0, NE)	43.0 (15.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.127
95% CI for the HR		(0.7263 , 1.7492)
p-value for the HR		0.5937

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.1.2.2 .2 .2 .3 Abstammung

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	26 (81.3)	29 (93.5)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	14.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 45.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	45.0 (15.0 , 46.0)	43.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.043
95% CI for the HR		(0.6122 , 1.7778)
p-value for the HR		0.8763

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	31 (77.5)	36 (81.8)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	43.0 (15.0, NE)	43.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.998
95% CI for the HR		(0.6107 , 1.6303)
p-value for the HR		0.9930

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.1.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	9 (69.2)	14 (87.5)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (15.0 , 16.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	16.0 (15.0, NE)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	15.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.673
95% CI for the HR		(0.6865 , 4.0787)
p-value for the HR		0.2574

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 2 of 2

Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	50 (80.6)	52 (86.7)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	45.0 (15.0 , 46.0)	43.0 (16.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.886
95% CI for the HR		(0.5987 , 1.3099)
p-value for the HR		0.5430

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.1.2.2 .2 .2 .5 BMI

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

Page: 1 of 3

BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	16 (76.2)	12 (92.3)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (15.0 , 17.0)
75th percentile - Q3 (95% CI)	30.5 (15.0, NE)	17.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.951
95% CI for the HR		(0.4300 , 2.1039)
p-value for the HR		0.9016

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	16 (80.0)	17 (81.0)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 45.0)	15.0 (4.0 , 46.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	46.5 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.127
95% CI for the HR		(0.5625 , 2.2566)
p-value for the HR		0.7365

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	27 (79.4)	37 (88.1)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 16.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	43.0 (15.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.031
95% CI for the HR		(0.6168 , 1.7231)
p-value for the HR		0.9074

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.1.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	25 (78.1)	30 (93.8)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 45.0)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	18.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.228
95% CI for the HR		(0.7086 , 2.1276)
p-value for the HR		0.4642

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	34 (79.1)	36 (81.8)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	14.0 (3.0 , 15.0)	15.0 (NE, NE)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	42.0 (15.0, NE)	43.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.857
95% CI for the HR		(0.5351 , 1.3738)
p-value for the HR		0.5224

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.1.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	9 (90.0)	8 (80.0)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 16.0)	15.0 (3.0 , 42.0)
50th percentile - median (95% CI)	15.5 (3.0, NE)	28.5 (3.0, NE)
75th percentile - Q3 (95% CI)	46.0 (15.0, NE)	47.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.808
95% CI for the HR		(0.1970 , 3.3174)
p-value for the HR		0.7677

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	50 (76.9)	58 (87.9)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	14.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	43.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.068
95% CI for the HR		(0.7273 , 1.5684)
p-value for the HR		0.7370

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.1.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	48 (81.4)	57 (86.4)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	45.0 (16.0, NE)	43.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.021
95% CI for the HR		(0.6919 , 1.5063)
p-value for the HR		0.9171

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	11 (68.8)	9 (90.0)
Time to first Mental Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 45.0)	15.0 (3.0 , 47.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	47.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.516
95% CI for the HR		(0.4911 , 4.6805)
p-value for the HR		0.4694

NOTE 1: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.

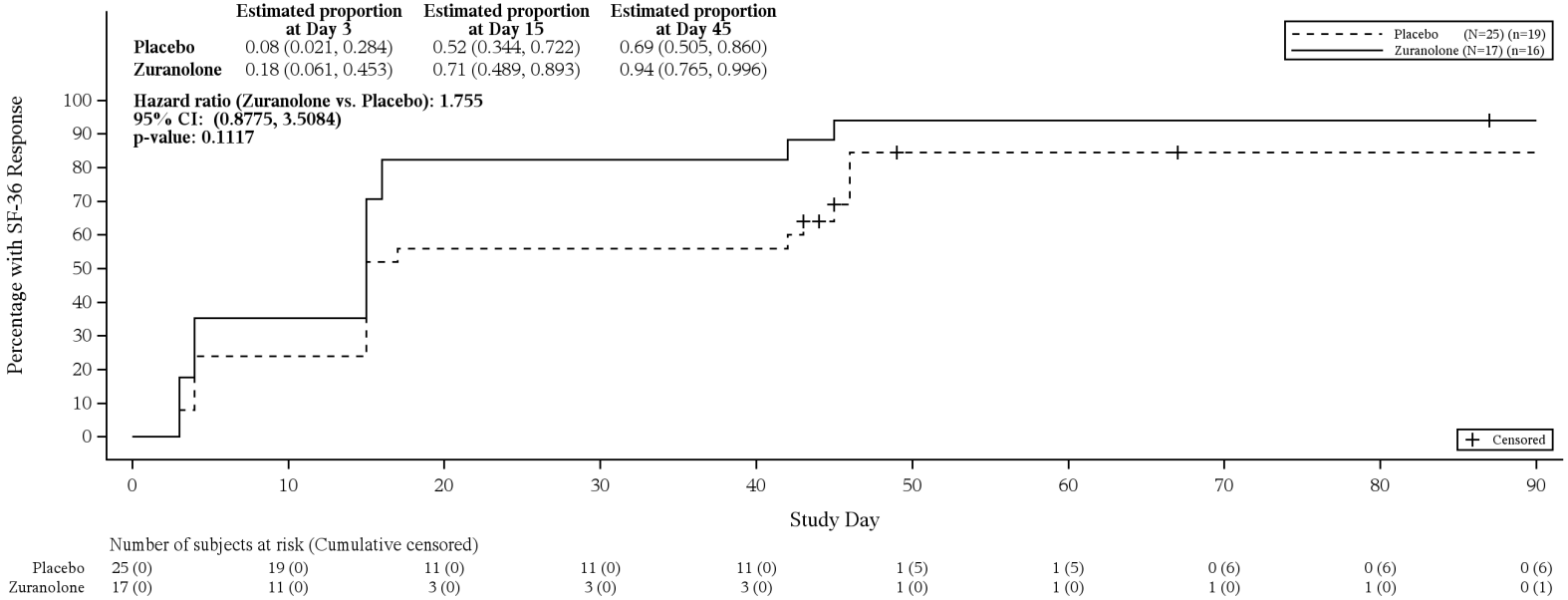
Source: biib125/v_a/germany_amnog/t-sf36-ment-resp15-tte-201-by.sas:t-sf36-ment-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.1.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

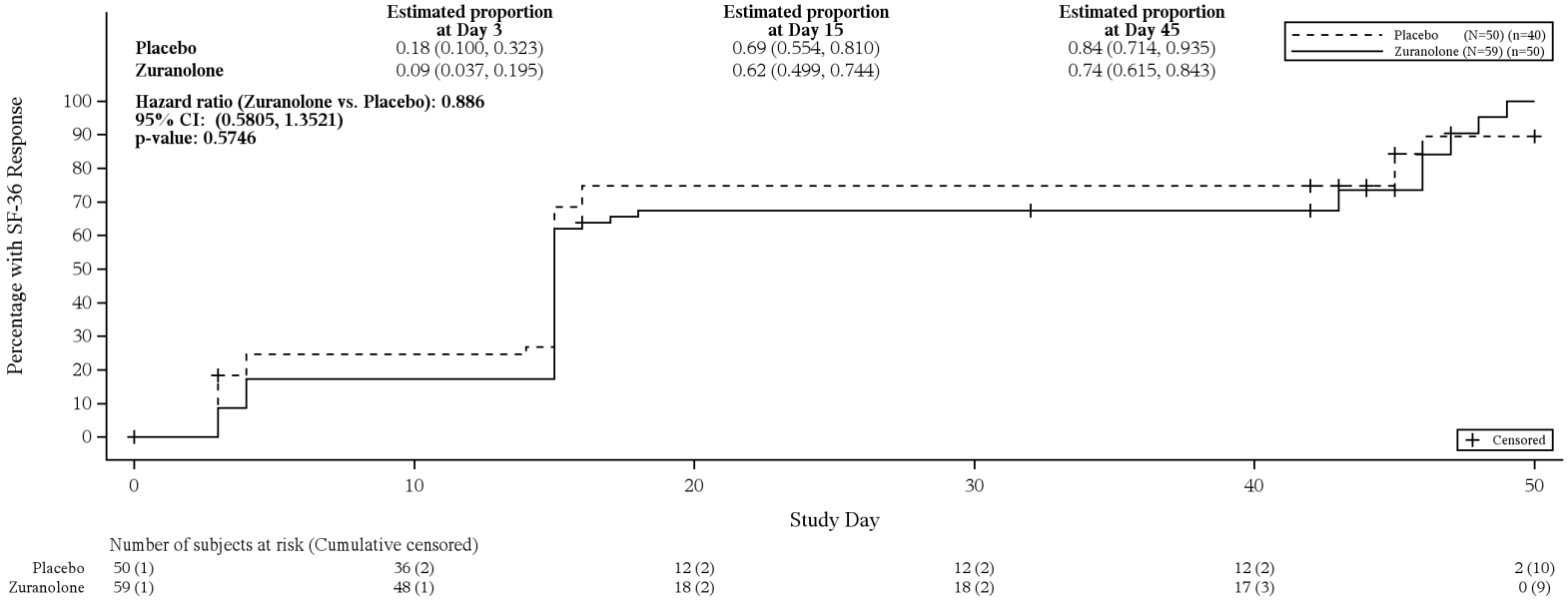
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-ment-resp15-tte-201-by.sas:f-sf36-ment-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 25-45



Number of subjects at risk (Cumulative censored)

Placebo	50 (1)	36 (2)	12 (2)	12 (2)	12 (2)	2 (10)
Zuranolone	59 (1)	48 (1)	18 (2)	18 (2)	17 (3)	0 (9)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

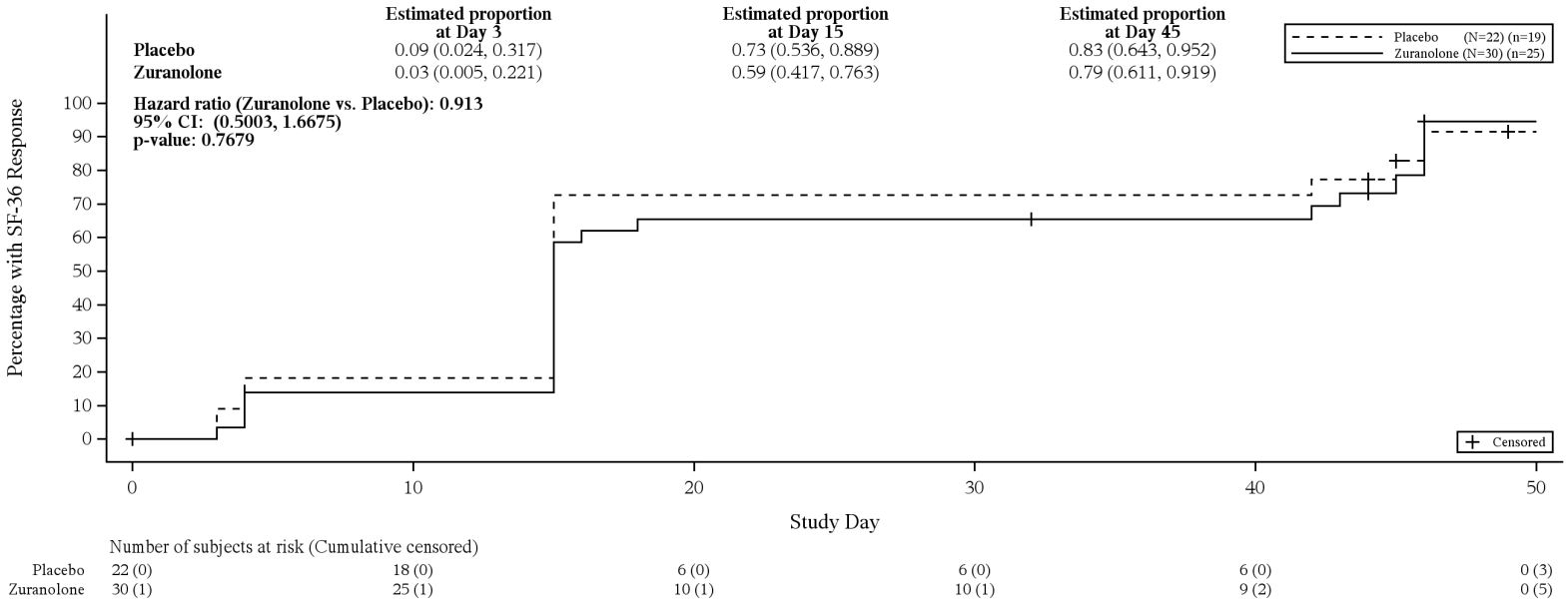
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	18 (0)	6 (0)	6 (0)	6 (0)	0 (3)
Zuranolone	30 (1)	25 (1)	10 (1)	10 (1)	9 (2)	0 (5)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

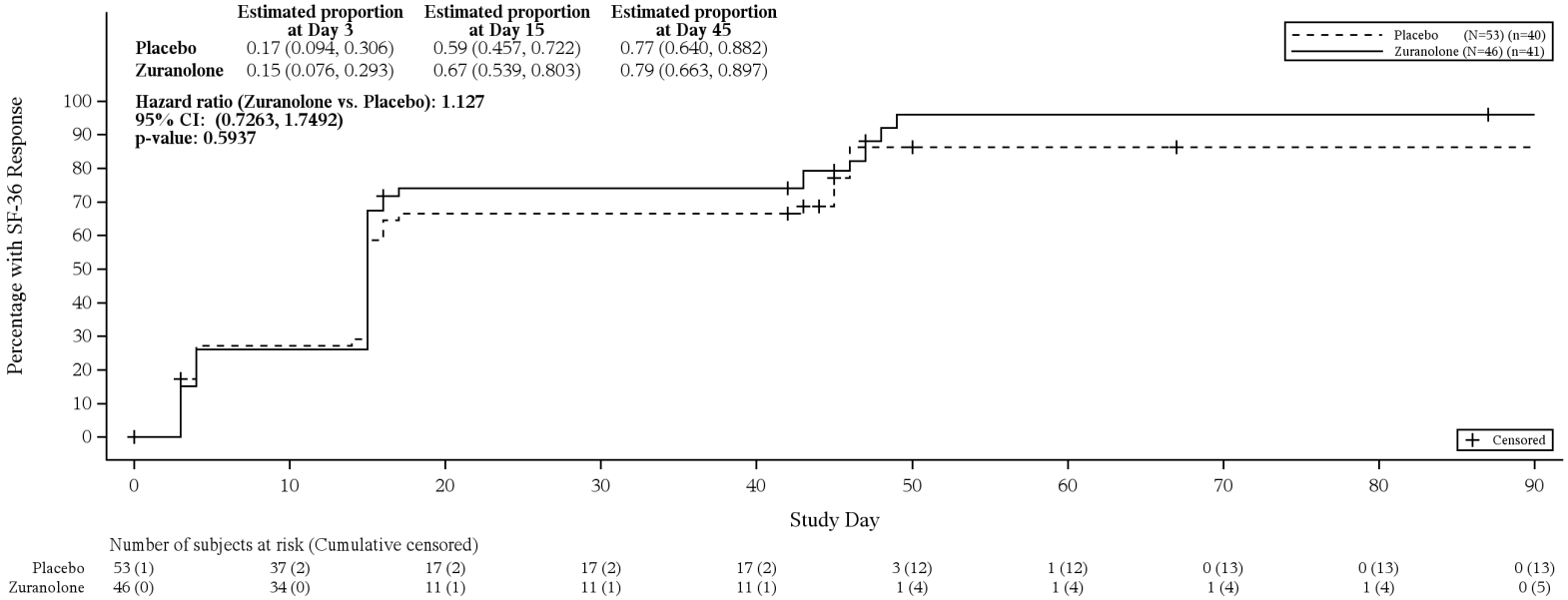
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

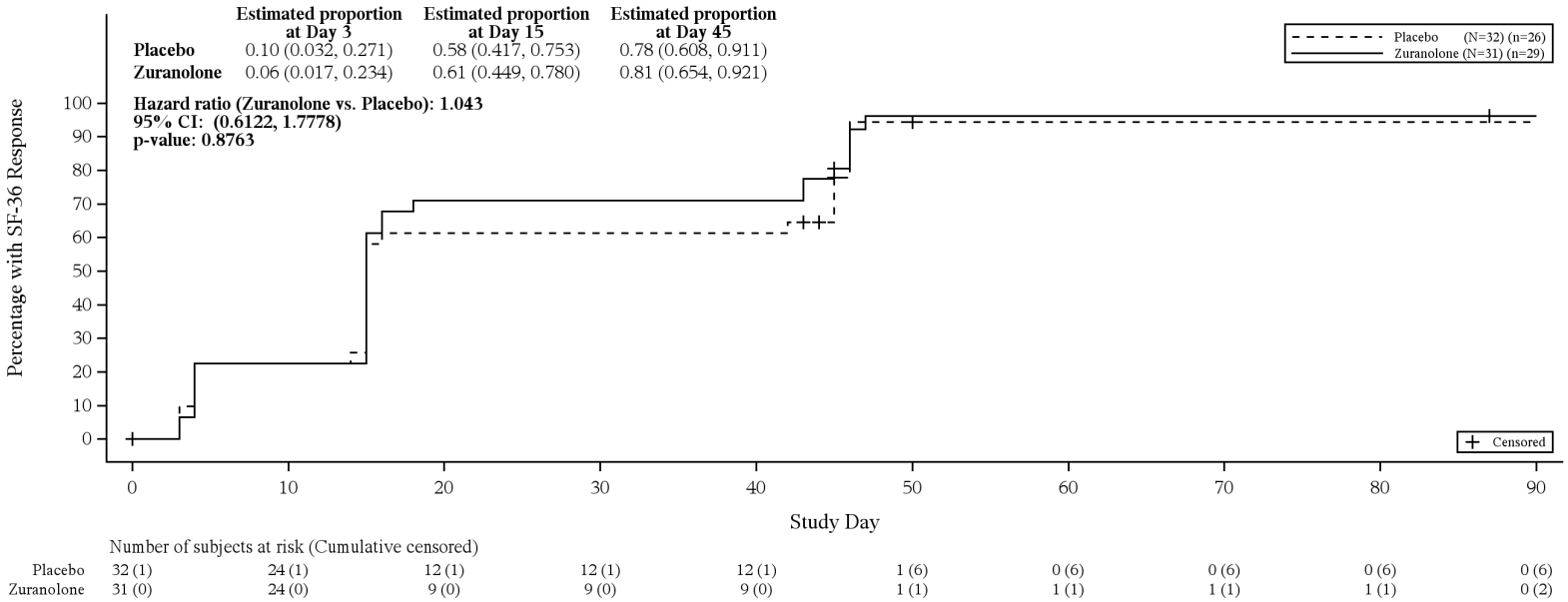
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

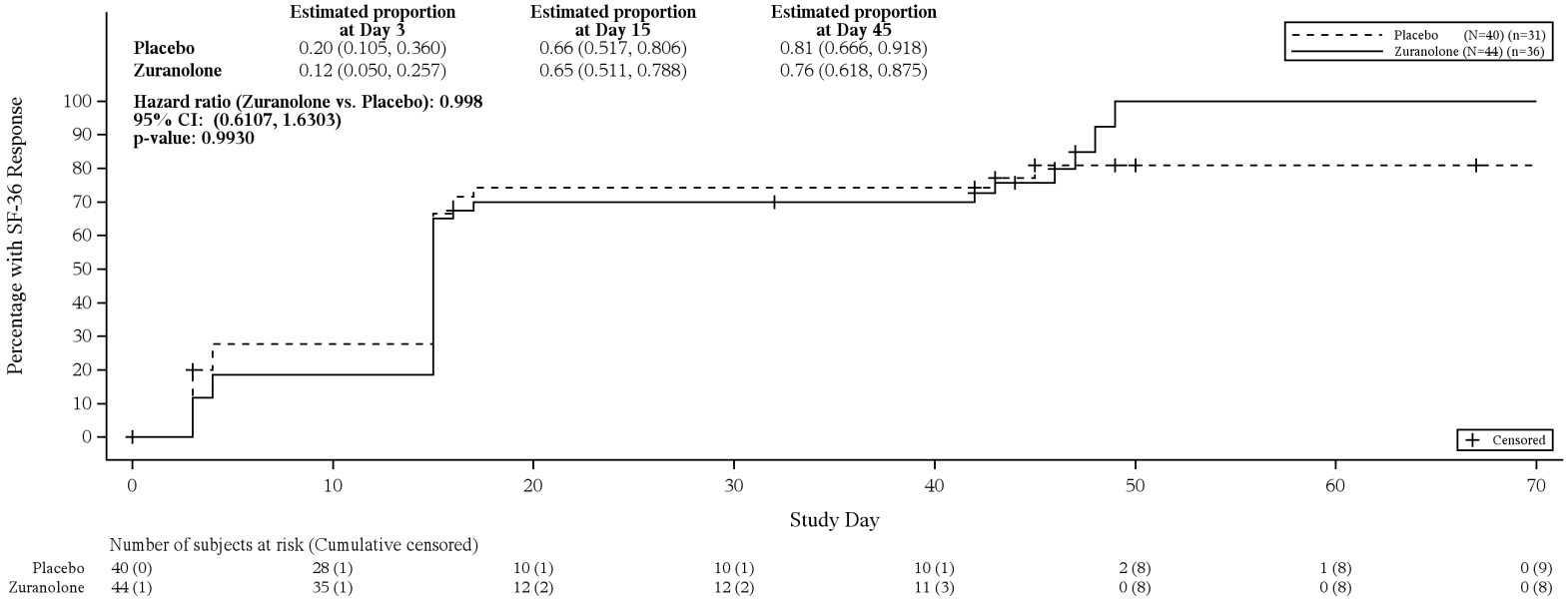
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

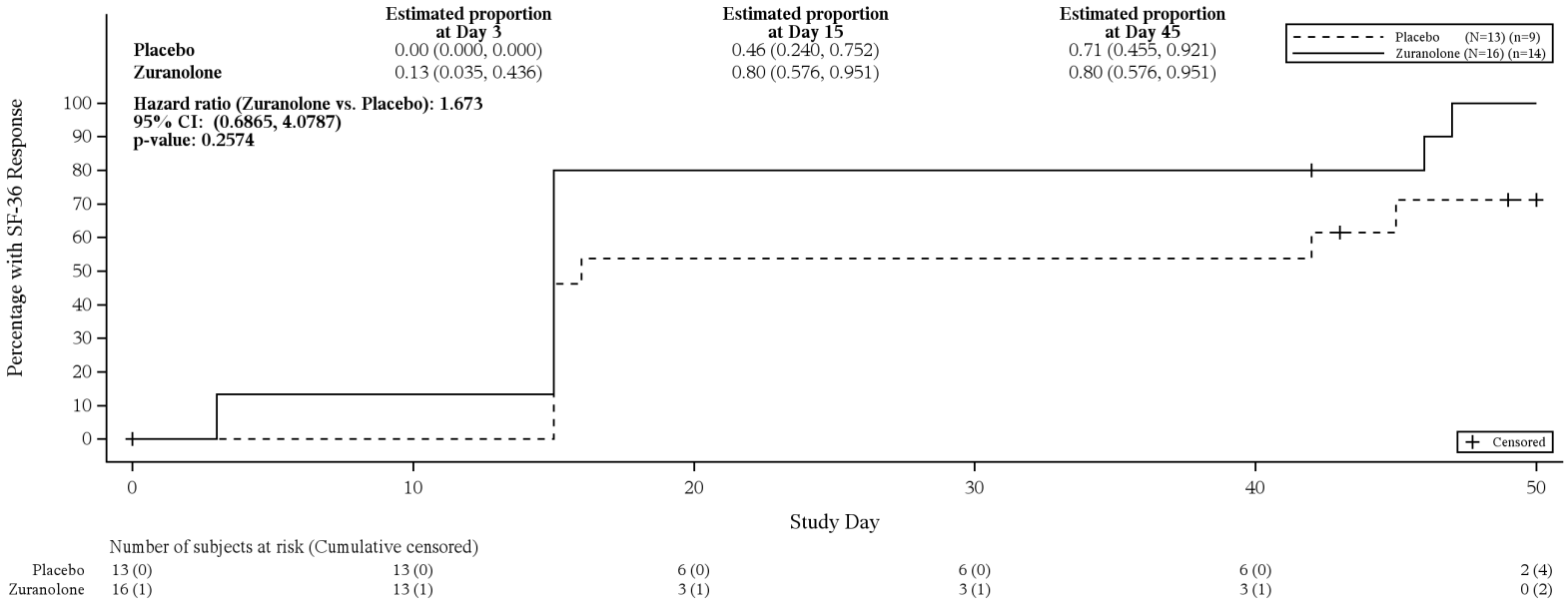
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	13 (0)	13 (0)	6 (0)	6 (0)	6 (0)	2 (4)
Zuranolone	16 (1)	13 (1)	3 (1)	3 (1)	3 (1)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

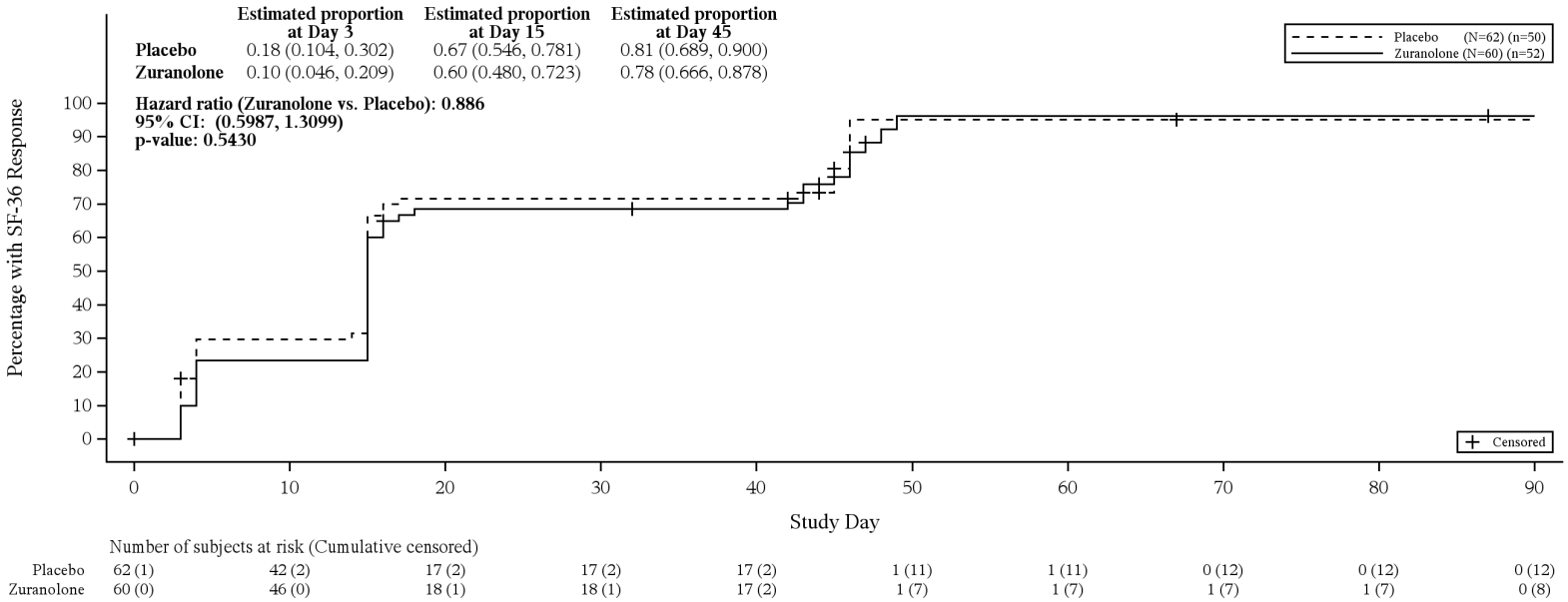
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

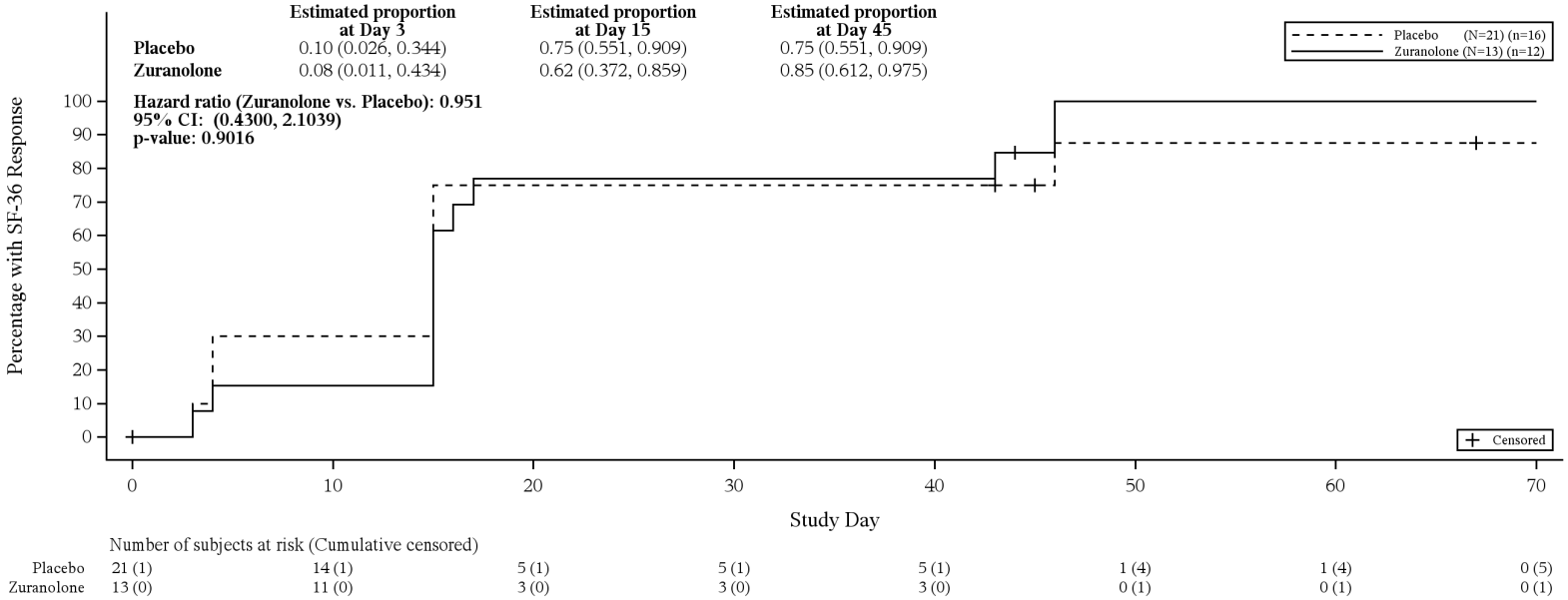
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Number of subjects at risk (Cumulative censored)

Placebo	21 (1)	14 (1)	5 (1)	5 (1)	5 (1)	1 (4)	1 (4)	0 (5)
Zuranolone	13 (0)	11 (0)	3 (0)	3 (0)	3 (0)	0 (1)	0 (1)	0 (1)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

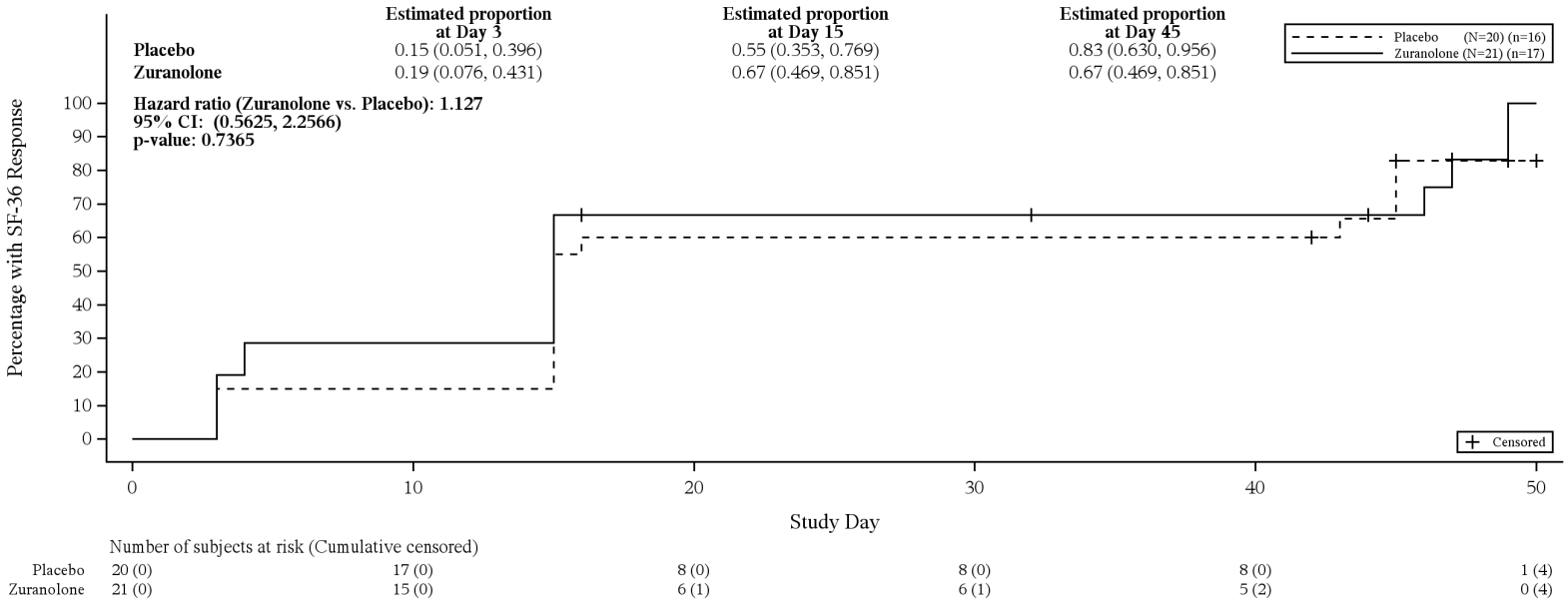
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Number of subjects at risk (Cumulative censored)

Placebo	20 (0)	17 (0)	8 (0)	8 (0)	8 (0)	1 (4)
Zuranolone	21 (0)	15 (0)	6 (1)	6 (1)	5 (2)	0 (4)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

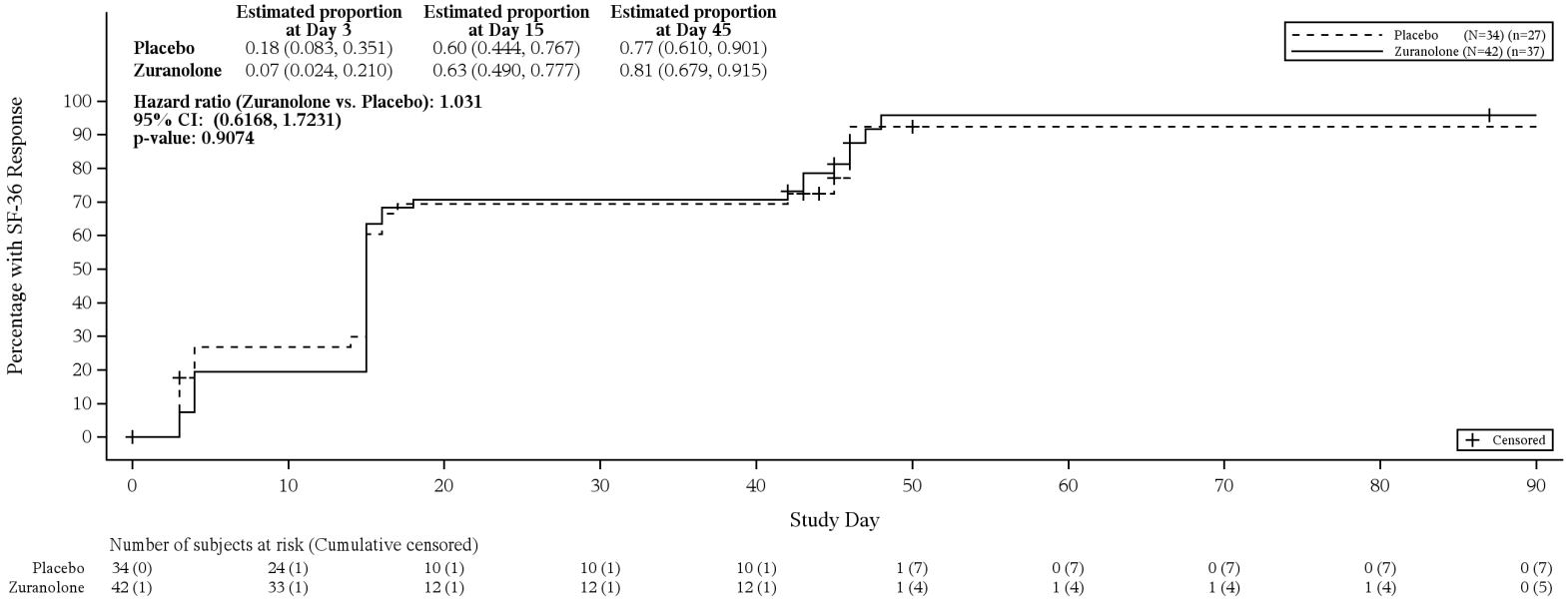
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

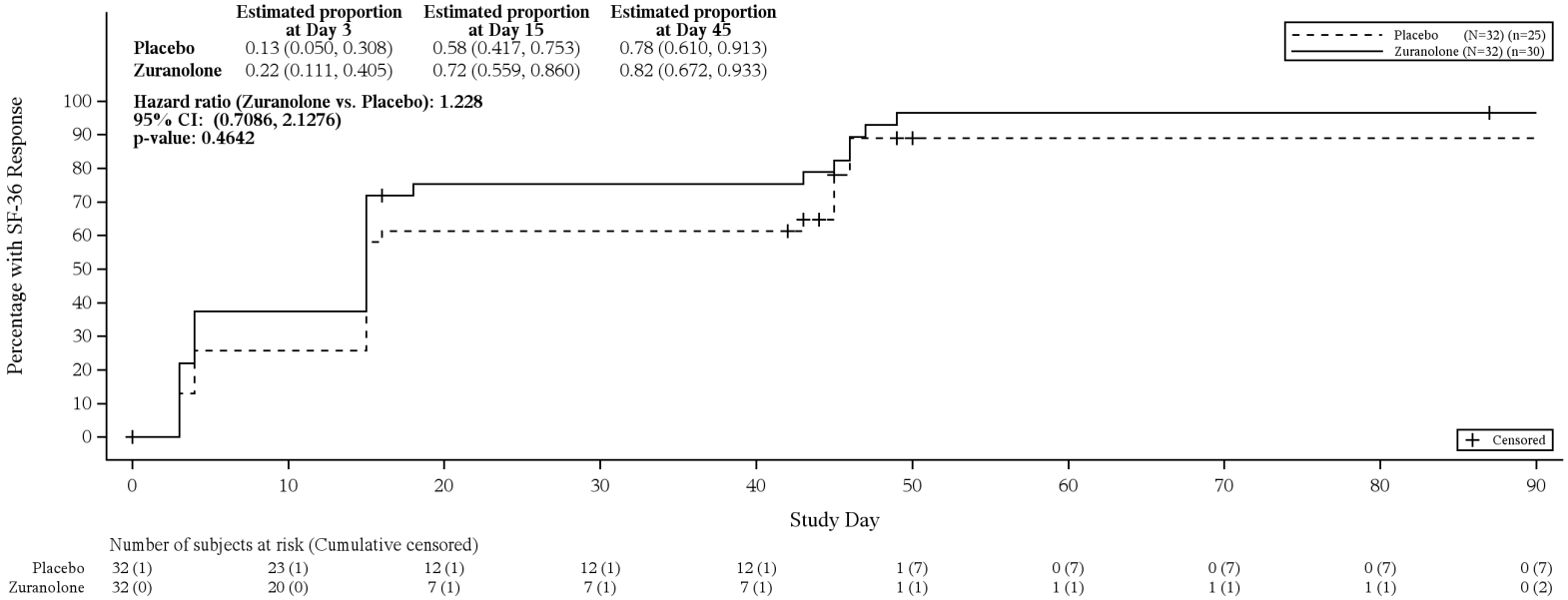
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

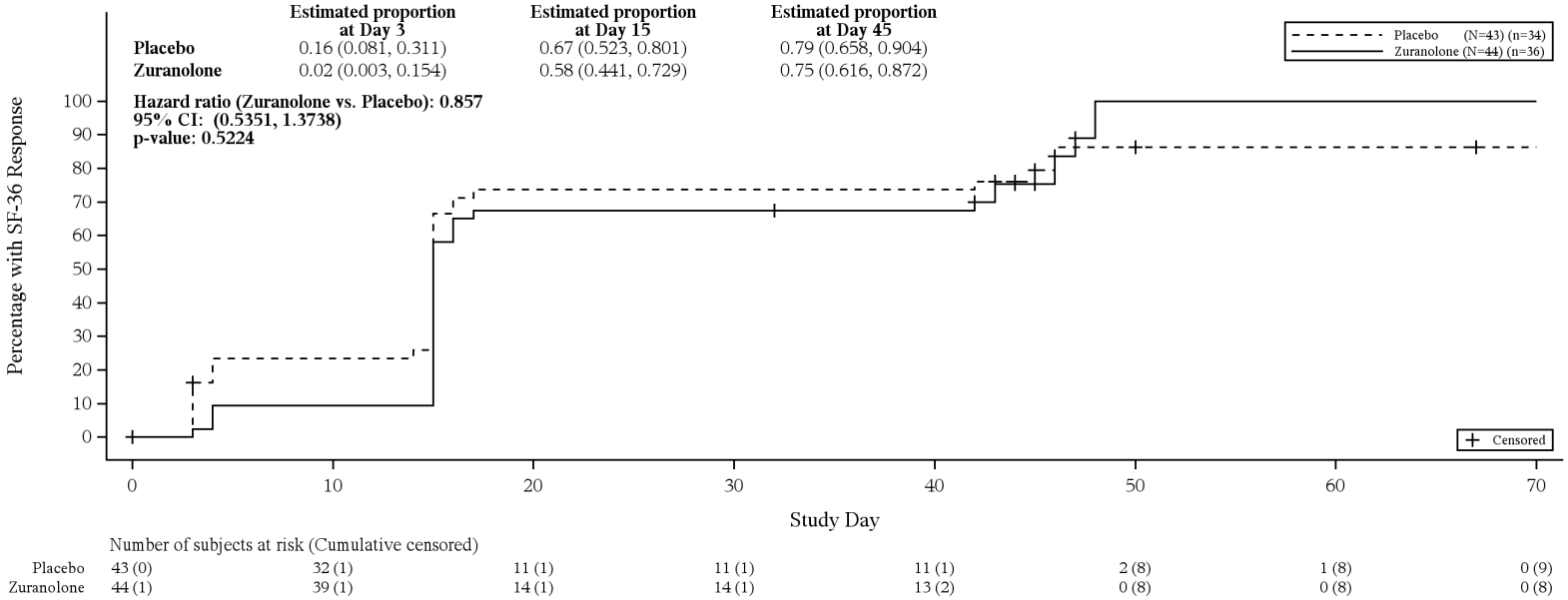
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 13 of 17

Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

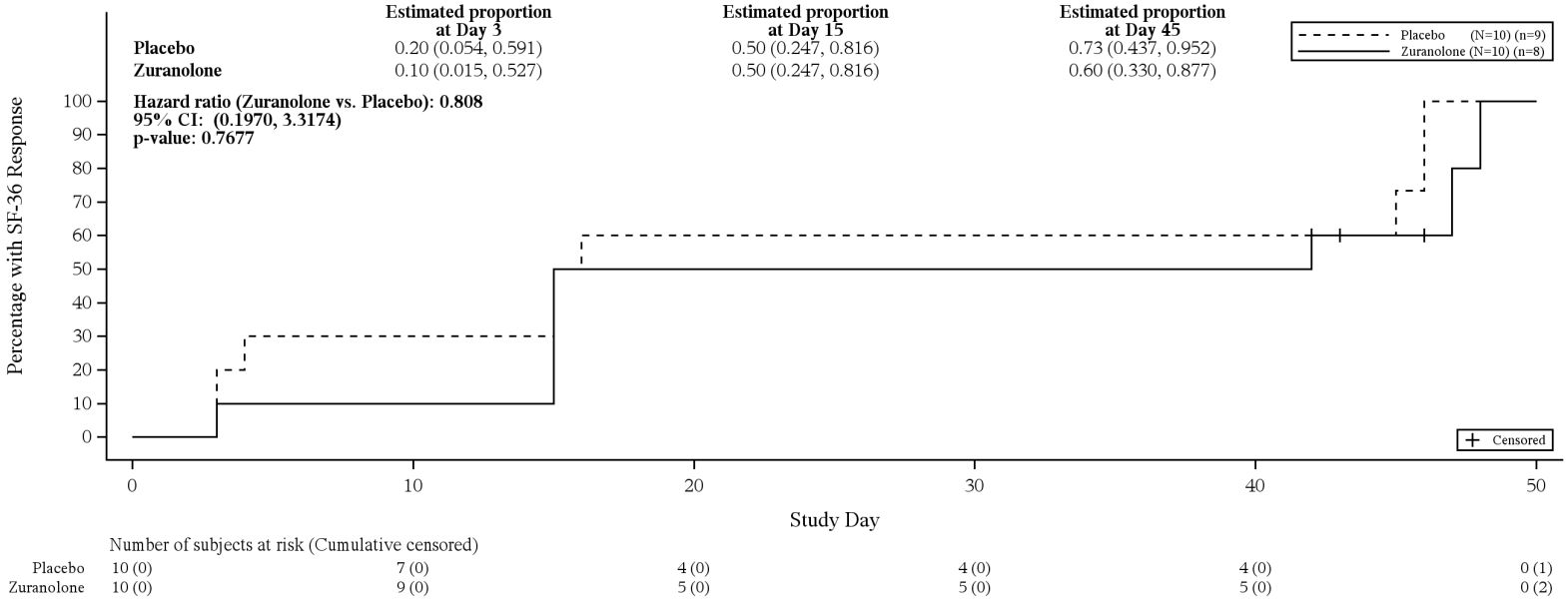
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Number of subjects at risk (Cumulative censored)

Placebo	10 (0)	7 (0)	4 (0)	4 (0)	4 (0)	0 (1)
Zuranolone	10 (0)	9 (0)	5 (0)	5 (0)	5 (0)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

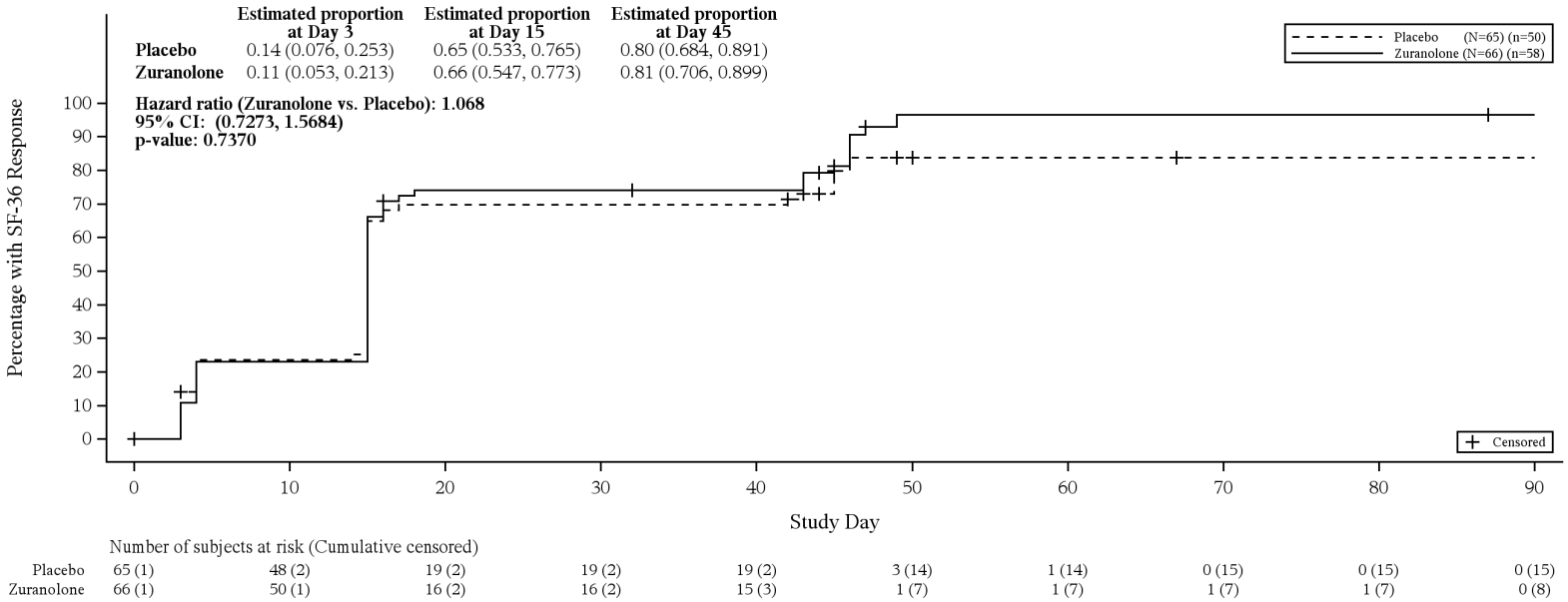
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

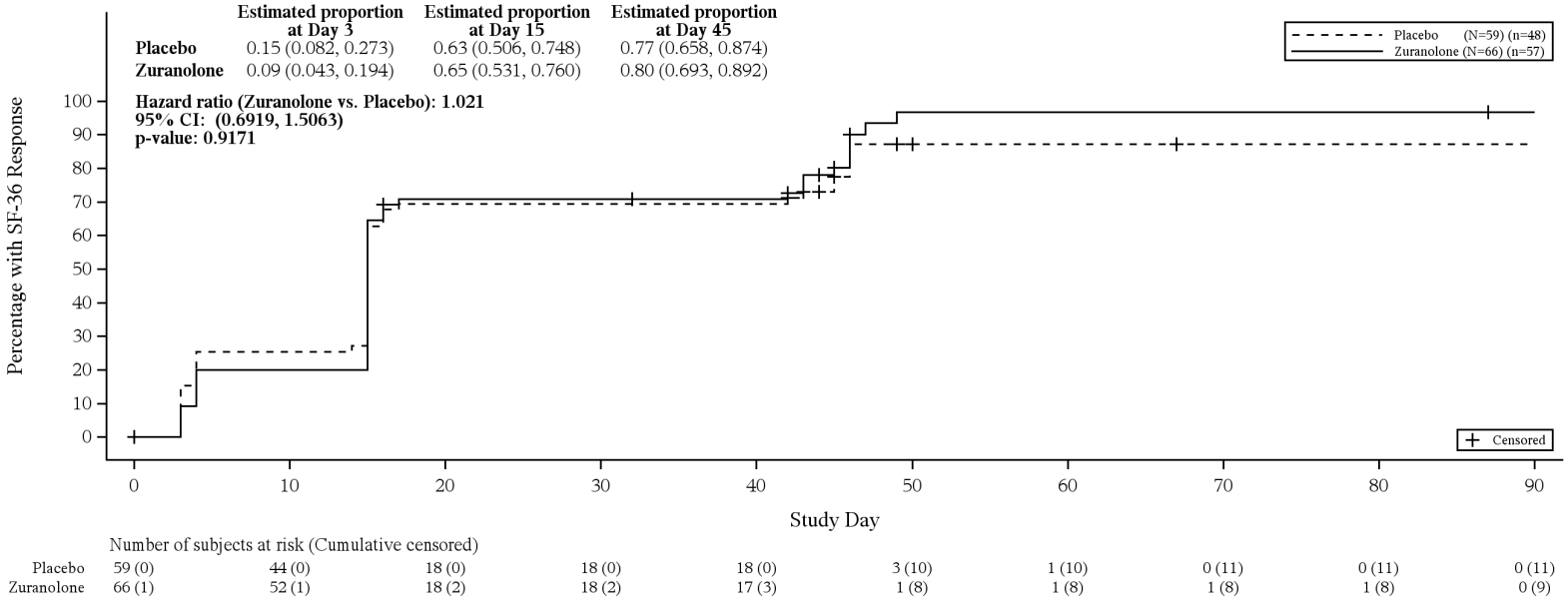
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

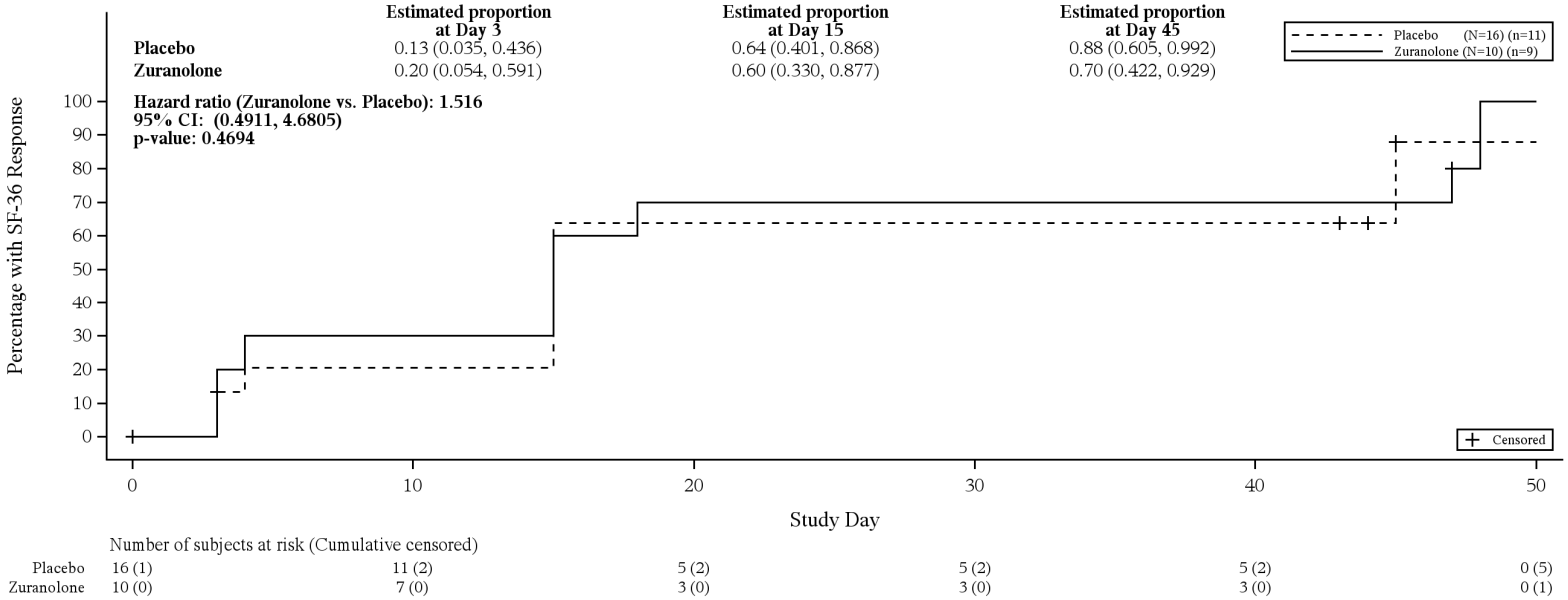
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-ment-resp15-tte-201-by.sas:f-sf36-ment-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Number of subjects at risk (Cumulative censored)

Placebo	16 (1)	11 (2)	5 (2)	5 (2)	5 (2)	0 (5)
Zuranolone	10 (0)	7 (0)	3 (0)	3 (0)	3 (0)	0 (1)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Mental Component Summary score response is defined as 9.6 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-ment-resp15-tte-201-by.sas:f-sf36-ment-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

2.1.3 Verschlechterung

2.1.3.1 Responder-Analysen

2.1.3.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Mental Component Summary Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with worsening, n (%) [2]	1 (1.3)	2 (2.6)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.97
95% CI for the RR		(0.183, 21.308)
p-value for RR		0.5754
OR - Odds Ratio (Zuranolone vs. Placebo)		2.00
95% CI for the OR		(0.177, 22.536)
p-value for OR		0.5749
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.031, 0.057)
p-value for ARR		0.5663

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Mental Component Summary score worsening (9.6 points (15% of total scale range) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-ment-wors15-201-ovr.sas:t-sf36-ment-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	0	1 (1.3)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		2.96
95% CI for the RR		(0.123, 71.552)
p-value for RR		0.5041
OR - Odds Ratio (Zuranolone vs. Placebo)		3.00
95% CI for the OR		(0.120, 74.819)
p-value for OR		0.5032
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.023, 0.049)
p-value for ARR		0.4803

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Mental Component Summary score worsening (9.6 points (15% of total scale range) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-ment-wors15-201-ovr.sas:t-sf36-ment-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.1.3.1 .2 Subgruppen

2.1.3.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Mental Component Summary Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	1 (1.3)	2 (2.6)	
Number of subjects with response at Day 45, n (%)	0	1 (1.3)	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	0/25	0/17	
25 - 45, n / N (%)	1/50 (2.0)	2/59 (3.4)	
Day 45			
18 - 24, n / N (%)	0/25	0/17	
25 - 45, n / N (%)	0/50	1/59 (1.7)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score worsening is defined as 9.6 points (15% of total scale range) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-wors15-201-int.sas:t-sf36-ment-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	0/22	1/30 (3.3)	
>=28, n / N (%)	1/53 (1.9)	1/46 (2.2)	
Day 45			
<28, n / N (%)	0/22	0/30	
>=28, n / N (%)	0/53	1/46 (2.2)	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	1/32 (3.1)	0/31	
White, n / N (%)	0/40	2/44 (4.5)	
Day 45			
Black or African American, n / N (%)	0/32	1/31 (3.2)	
White, n / N (%)	0/40	0/44	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score worsening is defined as 9.6 points (15% of total scale range) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-wors15-201-int.sas:t-sf36-ment-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	1/13 (7.7)	0/16	
No, n / N (%)	0/62	2/60 (3.3)	
Day 45			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	0/62	1/60 (1.7)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score worsening is defined as 9.6 points (15% of total scale range) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-wors15-201-int.sas:t-sf36-ment-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	0/21	0/13	
25-29.9, n / N (%)	1/20 (5.0)	1/21 (4.8)	
>=30, n / N (%)	0/34	1/42 (2.4)	
Day 45			
<=24.9, n / N (%)	0/21	0/13	
25-29.9, n / N (%)	0/20	0/21	
>=30, n / N (%)	0/34	1/42 (2.4)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score worsening is defined as 9.6 points (15% of total scale range) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-wors15-201-int.sas:t-sf36-ment-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	0/32	0/32	
Postpartum, n / N (%)	1/43 (2.3)	2/44 (4.5)	
Day 45			
3rd Trimester, n / N (%)	0/32	0/32	
Postpartum, n / N (%)	0/43	1/44 (2.3)	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	1/65 (1.5)	2/66 (3.0)	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	0/65	1/66 (1.5)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score worsening is defined as 9.6 points (15% of total scale range) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-wors15-201-int.sas:t-sf36-ment-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Component Summary Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 6 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	1/59 (1.7)	1/66 (1.5)	
Recurrent Episode, n / N (%)	0/16	1/10 (10.0)	
Day 45			
1st Episode, n / N (%)	0/59	1/66 (1.5)	
Recurrent Episode, n / N (%)	0/16	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/8	1/10 (10.0)	
>=20, n / N (%)	1/67 (1.5)	1/66 (1.5)	
Day 45			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	0/67	1/66 (1.5)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score worsening is defined as 9.6 points (15% of total scale range) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-wors15-201-int.sas:t-sf36-ment-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

2.1.3.1 .2 .2 Subgruppenanalysen

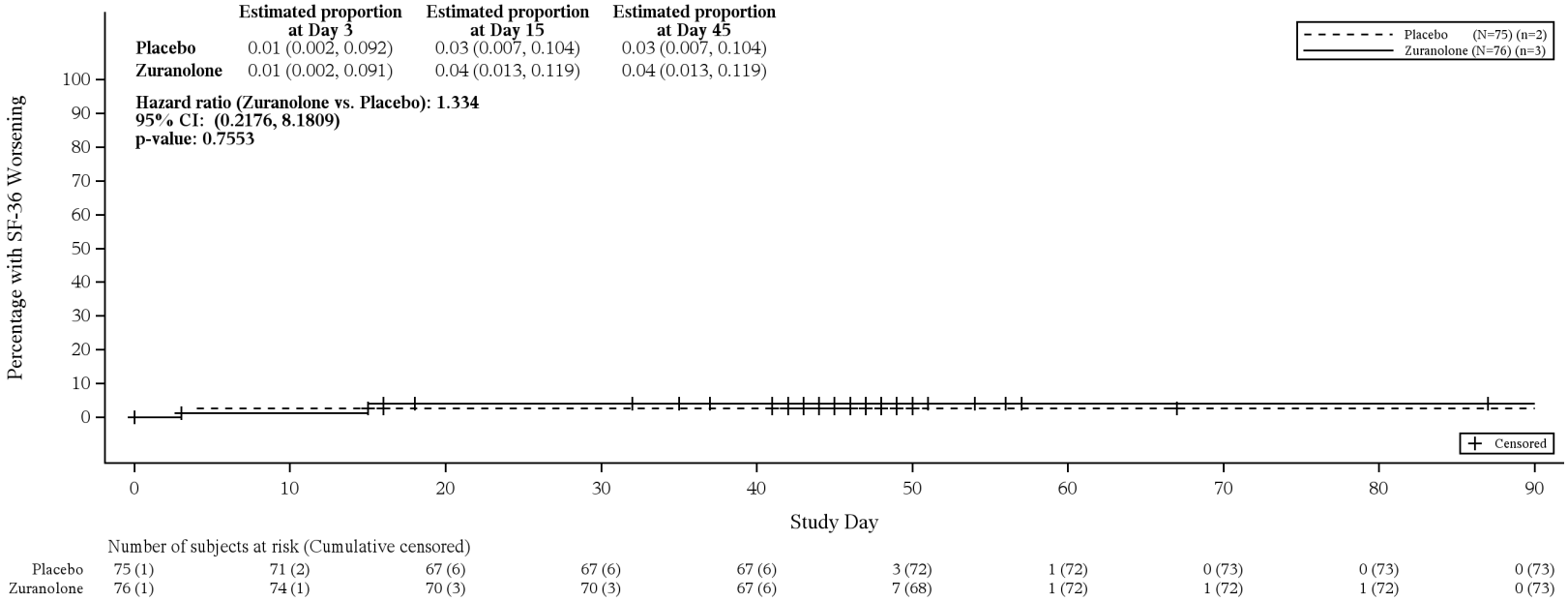
Nicht zutreffend.

2.1.3.2 TTE-Analysen

2.1.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Component Summary Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing SF-36 Mental Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 Mental Component Summary score worsening is defined as 9.6 points (15% of total scale range) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-ment-wors15-tte-201-by.sas:f-sf36-ment-wors15-tte-201-by-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	2 (2.7)	3 (3.9)
Time to first Mental Component Summary worsening (days) [3]		
25th percentile - Q1 (95% CI)	NE (NE, NE)	NE (NE, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.334
95% CI for the HR		(0.2176 , 8.1809)
p-value for the HR		0.7553

NOTE 1: SF-36 Mental Component Summary score worsening is defined as 9.6 points (15% of total scale range) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing SF-36 Mental Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Mental Component Summary score worsening. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Mental Component Summary score, and treatment.
Source: biib125/v_a/germany_amnog/t-sf36-ment-wors15-tte-201-ovr.sas:t-sf36-ment-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.1.3.2 .2 Subgruppen

2.1.3.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	2 (2.7)	3 (3.9)	
Age Group (years)			
18 - 24, n / N (%)	0/25	0/17	NA
25 - 45, n / N (%)	2/50 (4.0)	3/59 (5.1)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	0/22	1/30 (3.3)	NA
>=28, n / N (%)	2/53 (3.8)	2/46 (4.3)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	1/32 (3.1)	1/31 (3.2)	NA
White, n / N (%)	0/40	2/44 (4.5)	
Antidepressant Use at Baseline			
Yes, n / N (%)	1/13 (7.7)	0/16	NA
No, n / N (%)	1/62 (1.6)	3/60 (5.0)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score worsening is defined as 9.6 points (15% of total scale range) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-wors15-tte-201-int.sas:t-sf36-ment-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Component Summary Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	0/21	0/13	NA(a)
25-29.9, n / N (%)	1/20 (5.0)	1/21 (4.8)	NA(b)
>=30, n / N (%)	1/34 (2.9)	2/42 (4.8)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	0/32	0/32	NA
Postpartum, n / N (%)	2/43 (4.7)	3/44 (6.8)	
Family History of PPD			
Yes, n / N (%)	0/10	0/10	NA
No/Unknown, n / N (%)	2/65 (3.1)	3/66 (4.5)	
History of PPD			
1st Episode, n / N (%)	2/59 (3.4)	2/66 (3.0)	NA
Recurrent Episode, n / N (%)	0/16	1/10 (10.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/8	1/10 (10.0)	NA
>=20, n / N (%)	2/67 (3.0)	2/66 (3.0)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Mental Component Summary score worsening is defined as 9.6 points (15% of total scale range) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-ment-wors15-tte-201-int.sas:t-sf36-ment-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.1.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

2.1.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

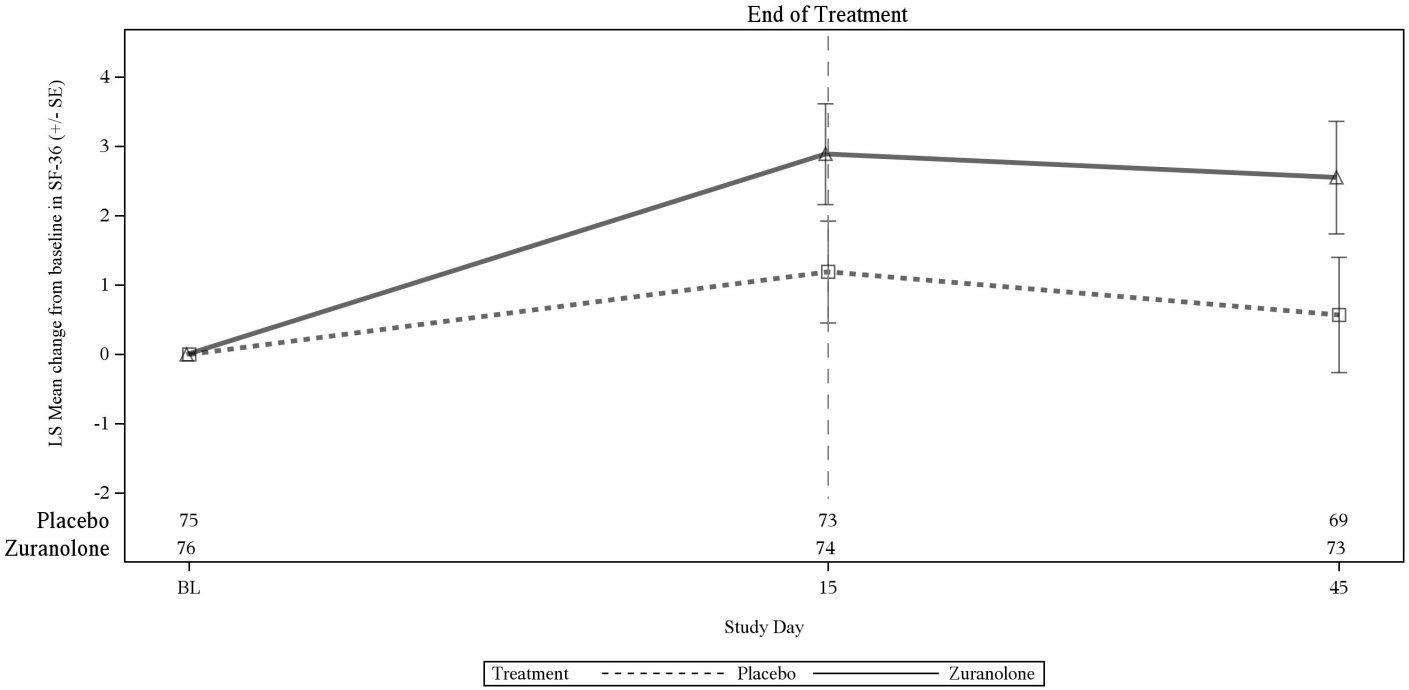
2.2 PCS

2.2.1 MMRM

2.2.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-ovr.sas:f-sf36-phys-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary: 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	1.19 (0.734)	2.89 (0.728)
95% CI for the LS Mean	-0.27, 2.64	1.45, 4.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.70 (1.035)
95% CI for the LS Mean		-0.34, 3.75
p-value		0.1024
Hedges' g (Zuranolone vs. Placebo)		0.270
95% CI for Hedges' g		-0.0550, 0.5945
Day 45		
n	69	73
LS Mean (SE)	0.57 (0.831)	2.55 (0.810)
95% CI for the LS Mean	-1.08, 2.21	0.95, 4.15
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.99 (1.162)
95% CI for the LS Mean		-0.31, 4.28
p-value		0.0897
Hedges' g (Zuranolone vs. Placebo)		0.285
95% CI for Hedges' g		-0.0454, 0.6161

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-ovr.sas:t-sf36-phys-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.2.1.2 Subgruppen

2.2.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.8499
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.0545
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.5584
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.7277
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-int.sas:t-sf36-phys-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.9677(a)
25-29.9	20	21	0.7644(b)
>=30	34	42	0.7786(c)
Onset of PPD			
3rd Trimester	32	32	0.8862
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.6387
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.2404
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-int.sas:t-sf36-phys-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

2.2.1.2 .2 Subgruppenanalysen

2.2.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	1.73 (1.436)	3.20 (1.750)
95% CI for the LS Mean	-1.17, 4.64	-0.34, 6.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.47 (2.316)
95% CI for the LS Mean		-3.21, 6.15
p-value		0.5296
Hedges' g (Zuranolone vs. Placebo)		0.196
95% CI for Hedges' g		-0.4219, 0.8132
Day 45		
n	25	16
LS Mean (SE)	0.15 (1.496)	2.83 (1.878)
95% CI for the LS Mean	-2.88, 3.17	-0.96, 6.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.69 (2.456)
95% CI for the LS Mean		-2.28, 7.65
p-value		0.2806
Hedges' g (Zuranolone vs. Placebo)		0.343
95% CI for Hedges' g		-0.2886, 0.9752

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	0.81 (0.877)	2.86 (0.803)
95% CI for the LS Mean	-0.93, 2.55	1.27, 4.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.05 (1.190)
95% CI for the LS Mean		-0.31, 4.41
p-value		0.0879
Hedges' g (Zuranolone vs. Placebo)		0.335
95% CI for Hedges' g		-0.0515, 0.7218
Day 45		
n	44	57
LS Mean (SE)	0.72 (1.018)	2.54 (0.901)
95% CI for the LS Mean	-1.30, 2.74	0.76, 4.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.83 (1.361)
95% CI for the LS Mean		-0.87, 4.53
p-value		0.1826
Hedges' g (Zuranolone vs. Placebo)		0.267
95% CI for Hedges' g		-0.1277, 0.6624

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.2.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	2.94 (1.494)	1.41 (1.311)
95% CI for the LS Mean	-0.07, 5.94	-1.23, 4.04
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.53 (2.010)
95% CI for the LS Mean		-5.57, 2.51
p-value		0.4501
Hedges' g (Zuranolone vs. Placebo)		-0.214
95% CI for Hedges' g		-0.7735, 0.3464
Day 45		
n	22	28
LS Mean (SE)	1.46 (1.361)	1.78 (1.197)
95% CI for the LS Mean	-1.27, 4.20	-0.63, 4.19
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.32 (1.841)
95% CI for the LS Mean		-3.38, 4.02
p-value		0.8642
Hedges' g (Zuranolone vs. Placebo)		0.048
95% CI for Hedges' g		-0.5102, 0.6067

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	0.40 (0.807)	3.81 (0.850)
95% CI for the LS Mean	-1.20, 2.01	2.12, 5.50
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.41 (1.173)
95% CI for the LS Mean		1.08, 5.74
p-value		0.0046
Hedges' g (Zuranolone vs. Placebo)		0.586
95% CI for Hedges' g		0.1794, 0.9934
Day 45		
n	47	45
LS Mean (SE)	0.13 (1.066)	3.10 (1.095)
95% CI for the LS Mean	-1.99, 2.25	0.92, 5.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.97 (1.529)
95% CI for the LS Mean		-0.07, 6.01
p-value		0.0554
Hedges' g (Zuranolone vs. Placebo)		0.401
95% CI for Hedges' g		-0.0114, 0.8144

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.2.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	2.79 (1.191)	3.78 (1.191)
95% CI for the LS Mean	0.41, 5.18	1.39, 6.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.98 (1.686)
95% CI for the LS Mean		-2.39, 4.36
p-value		0.5628
Hedges' g (Zuranolone vs. Placebo)		0.146
95% CI for Hedges' g		-0.3525, 0.6445
Day 45		
n	30	30
LS Mean (SE)	1.15 (1.247)	4.96 (1.247)
95% CI for the LS Mean	-1.34, 3.65	2.46, 7.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.80 (1.765)
95% CI for the LS Mean		0.27, 7.34
p-value		0.0354
Hedges' g (Zuranolone vs. Placebo)		0.549
95% CI for Hedges' g		0.0336, 1.0646

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	0.28 (0.980)	2.03 (0.940)
95% CI for the LS Mean	-1.67, 2.24	0.16, 3.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.74 (1.371)
95% CI for the LS Mean		-0.98, 4.47
p-value		0.2069
Hedges' g (Zuranolone vs. Placebo)		0.280
95% CI for Hedges' g		-0.1577, 0.7183
Day 45		
n	36	42
LS Mean (SE)	0.08 (1.163)	0.49 (1.088)
95% CI for the LS Mean	-2.24, 2.39	-1.67, 2.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.42 (1.604)
95% CI for the LS Mean		-2.78, 3.61
p-value		0.7956
Hedges' g (Zuranolone vs. Placebo)		0.058
95% CI for Hedges' g		-0.3868, 0.5037

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.2.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	1.03 (1.415)	1.40 (1.310)
95% CI for the LS Mean	-1.88, 3.95	-1.30, 4.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.36 (1.937)
95% CI for the LS Mean		-3.63, 4.36
p-value		0.8521
Hedges' g (Zuranolone vs. Placebo)		0.069
95% CI for Hedges' g		-0.6736, 0.8122
Day 45		
n	11	15
LS Mean (SE)	1.32 (1.758)	2.94 (1.562)
95% CI for the LS Mean	-2.29, 4.93	-0.28, 6.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.62 (2.358)
95% CI for the LS Mean		-3.23, 6.48
p-value		0.4978
Hedges' g (Zuranolone vs. Placebo)		0.264
95% CI for Hedges' g		-0.5169, 1.0458

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	1.24 (0.843)	3.26 (0.849)
95% CI for the LS Mean	-0.43, 2.91	1.58, 4.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.02 (1.197)
95% CI for the LS Mean		-0.35, 4.39
p-value		0.0944
Hedges' g (Zuranolone vs. Placebo)		0.307
95% CI for Hedges' g		-0.0543, 0.6686
Day 45		
n	58	58
LS Mean (SE)	0.45 (0.933)	2.44 (0.934)
95% CI for the LS Mean	-1.40, 2.30	0.59, 4.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.99 (1.321)
95% CI for the LS Mean		-0.62, 4.61
p-value		0.1343
Hedges' g (Zuranolone vs. Placebo)		0.278
95% CI for Hedges' g		-0.0875, 0.6439

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.2.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	-0.55 (1.434)	1.70 (1.784)
95% CI for the LS Mean	-3.48, 2.38	-1.94, 5.35
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.25 (2.296)
95% CI for the LS Mean		-2.44, 6.95
p-value		0.3341
Hedges' g (Zuranolone vs. Placebo)		0.341
95% CI for Hedges' g		-0.3618, 1.0444
Day 45		
n	18	12
LS Mean (SE)	-3.34 (1.704)	-0.95 (2.095)
95% CI for the LS Mean	-6.83, 0.15	-5.24, 3.34
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.39 (2.708)
95% CI for the LS Mean		-3.15, 7.93
p-value		0.3850
Hedges' g (Zuranolone vs. Placebo)		0.320
95% CI for Hedges' g		-0.4150, 1.0548

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	2.78 (1.539)	5.28 (1.531)
95% CI for the LS Mean	-0.34, 5.91	2.17, 8.38
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.50 (2.173)
95% CI for the LS Mean		-1.91, 6.91
p-value		0.2581
Hedges' g (Zuranolone vs. Placebo)		0.356
95% CI for Hedges' g		-0.2684, 0.9810
Day 45		
n	20	20
LS Mean (SE)	2.17 (1.817)	3.49 (1.807)
95% CI for the LS Mean	-1.52, 5.86	-0.18, 7.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.32 (2.564)
95% CI for the LS Mean		-3.89, 6.53
p-value		0.6102
Hedges' g (Zuranolone vs. Placebo)		0.159
95% CI for Hedges' g		-0.4613, 0.7802

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	0.81 (1.018)	2.39 (0.911)
95% CI for the LS Mean	-1.22, 2.83	0.58, 4.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.59 (1.373)
95% CI for the LS Mean		-1.15, 4.33
p-value		0.2514
Hedges' g (Zuranolone vs. Placebo)		0.268
95% CI for Hedges' g		-0.1928, 0.7280
Day 45		
n	31	41
LS Mean (SE)	1.44 (1.057)	3.41 (0.923)
95% CI for the LS Mean	-0.66, 3.55	1.57, 5.25
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.97 (1.409)
95% CI for the LS Mean		-0.84, 4.78
p-value		0.1665
Hedges' g (Zuranolone vs. Placebo)		0.329
95% CI for Hedges' g		-0.1404, 0.7987

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.2.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	1.97 (1.163)	3.21 (1.144)
95% CI for the LS Mean	-0.35, 4.30	0.92, 5.50
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.24 (1.638)
95% CI for the LS Mean		-2.04, 4.51
p-value		0.4538
Hedges' g (Zuranolone vs. Placebo)		0.188
95% CI for Hedges' g		-0.3073, 0.6827
Day 45		
n	29	30
LS Mean (SE)	1.47 (1.358)	3.95 (1.335)
95% CI for the LS Mean	-1.25, 4.19	1.27, 6.62
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.48 (1.910)
95% CI for the LS Mean		-1.35, 6.30
p-value		0.2000
Hedges' g (Zuranolone vs. Placebo)		0.333
95% CI for Hedges' g		-0.1807, 0.8471

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	0.65 (0.959)	2.60 (0.957)
95% CI for the LS Mean	-1.26, 2.55	0.69, 4.50
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.95 (1.356)
95% CI for the LS Mean		-0.75, 4.65
p-value		0.1541
Hedges' g (Zuranolone vs. Placebo)		0.311
95% CI for Hedges' g		-0.1192, 0.7414
Day 45		
n	40	43
LS Mean (SE)	-0.04 (1.027)	1.53 (0.995)
95% CI for the LS Mean	-2.08, 2.00	-0.45, 3.51
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.57 (1.432)
95% CI for the LS Mean		-1.28, 4.42
p-value		0.2751
Hedges' g (Zuranolone vs. Placebo)		0.239
95% CI for Hedges' g		-0.1930, 0.6712

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.2.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	0.80 (1.155)	2.30 (1.153)
95% CI for the LS Mean	-1.65, 3.25	-0.14, 4.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.51 (1.734)
95% CI for the LS Mean		-2.17, 5.18
p-value		0.3977
Hedges' g (Zuranolone vs. Placebo)		0.372
95% CI for Hedges' g		-0.5120, 1.2561
Day 45		
n	9	10
LS Mean (SE)	1.67 (1.817)	3.73 (1.727)
95% CI for the LS Mean	-2.17, 5.51	0.06, 7.40
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.06 (2.578)
95% CI for the LS Mean		-3.38, 7.50
p-value		0.4353
Hedges' g (Zuranolone vs. Placebo)		0.351
95% CI for Hedges' g		-0.5568, 1.2581

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	1.16 (0.826)	3.04 (0.818)
95% CI for the LS Mean	-0.48, 2.79	1.42, 4.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.88 (1.164)
95% CI for the LS Mean		-0.42, 4.19
p-value		0.1079
Hedges' g (Zuranolone vs. Placebo)		0.286
95% CI for Hedges' g		-0.0639, 0.6353
Day 45		
n	60	63
LS Mean (SE)	0.33 (0.924)	2.42 (0.904)
95% CI for the LS Mean	-1.50, 2.16	0.63, 4.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.09 (1.294)
95% CI for the LS Mean		-0.47, 4.66
p-value		0.1080
Hedges' g (Zuranolone vs. Placebo)		0.290
95% CI for Hedges' g		-0.0651, 0.6457

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.2.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	0.93 (0.845)	3.05 (0.809)
95% CI for the LS Mean	-0.74, 2.60	1.45, 4.65
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.12 (1.173)
95% CI for the LS Mean		-0.20, 4.44
p-value		0.0731
Hedges' g (Zuranolone vs. Placebo)		0.324
95% CI for Hedges' g		-0.0317, 0.6804
Day 45		
n	55	64
LS Mean (SE)	0.50 (0.952)	3.02 (0.888)
95% CI for the LS Mean	-1.38, 2.39	1.26, 4.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.51 (1.304)
95% CI for the LS Mean		-0.07, 5.10
p-value		0.0563
Hedges' g (Zuranolone vs. Placebo)		0.352
95% CI for Hedges' g		-0.0109, 0.7153

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-phys-mmrm-201-by.sas:t-sf36-phys-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	2.11 (1.482)	2.03 (1.772)
95% CI for the LS Mean	-0.98, 5.19	-1.66, 5.72
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.08 (2.378)
95% CI for the LS Mean		-5.03, 4.87
p-value		0.9731
Hedges' g (Zuranolone vs. Placebo)		-0.014
95% CI for Hedges' g		-0.8252, 0.7979
Day 45		
n	14	9
LS Mean (SE)	0.70 (1.692)	-0.53 (2.100)
95% CI for the LS Mean	-2.82, 4.22	-4.88, 3.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.23 (2.758)
95% CI for the LS Mean		-6.95, 4.49
p-value		0.6608
Hedges' g (Zuranolone vs. Placebo)		-0.183
95% CI for Hedges' g		-1.0222, 0.6559

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

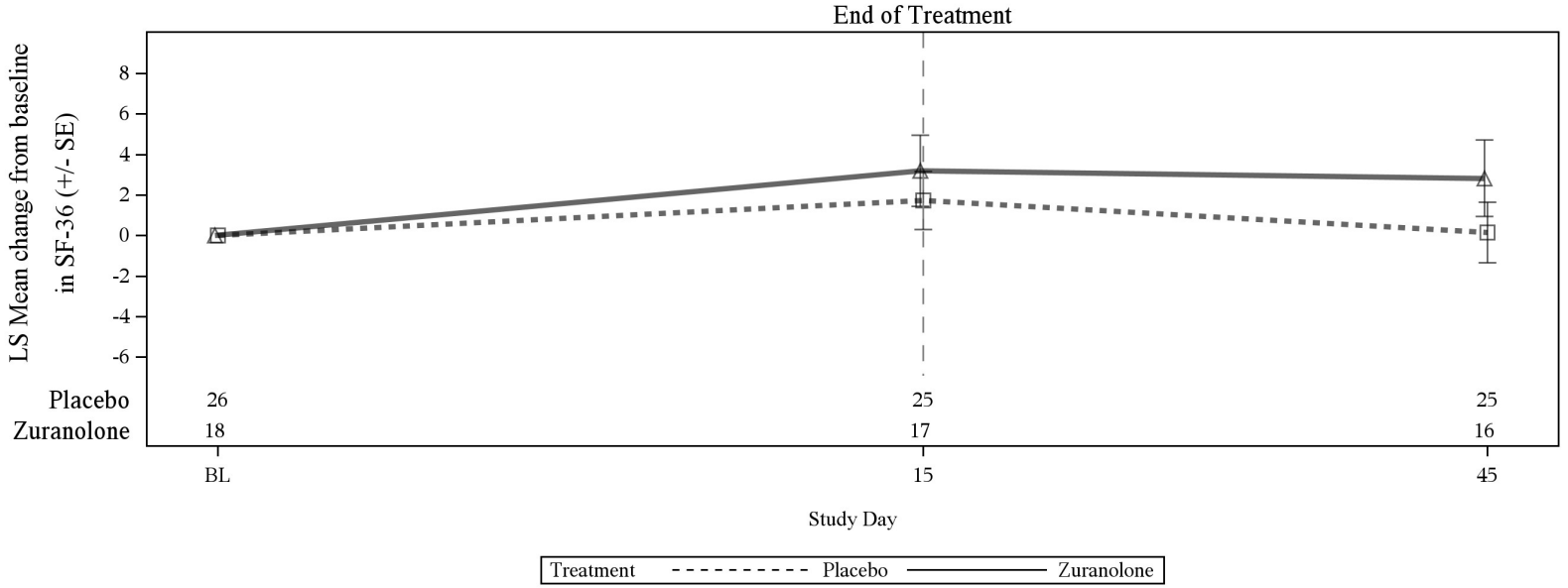
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2.2.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

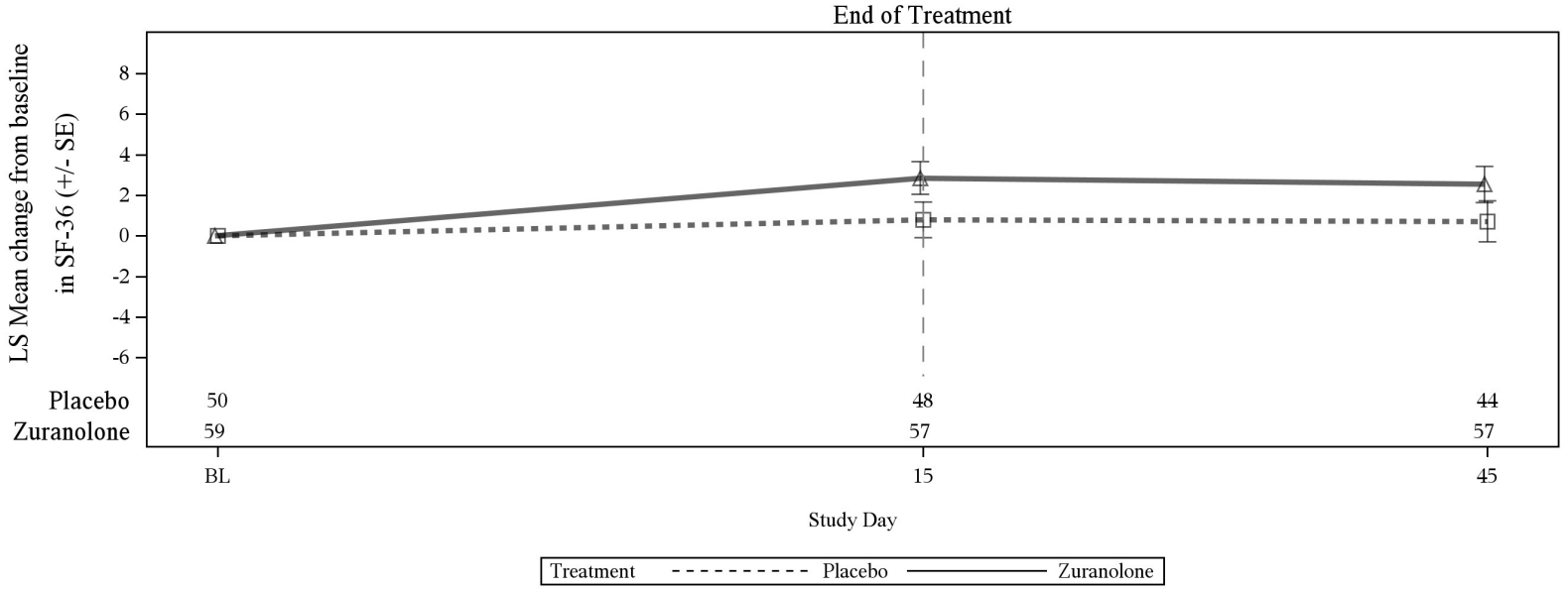
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Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

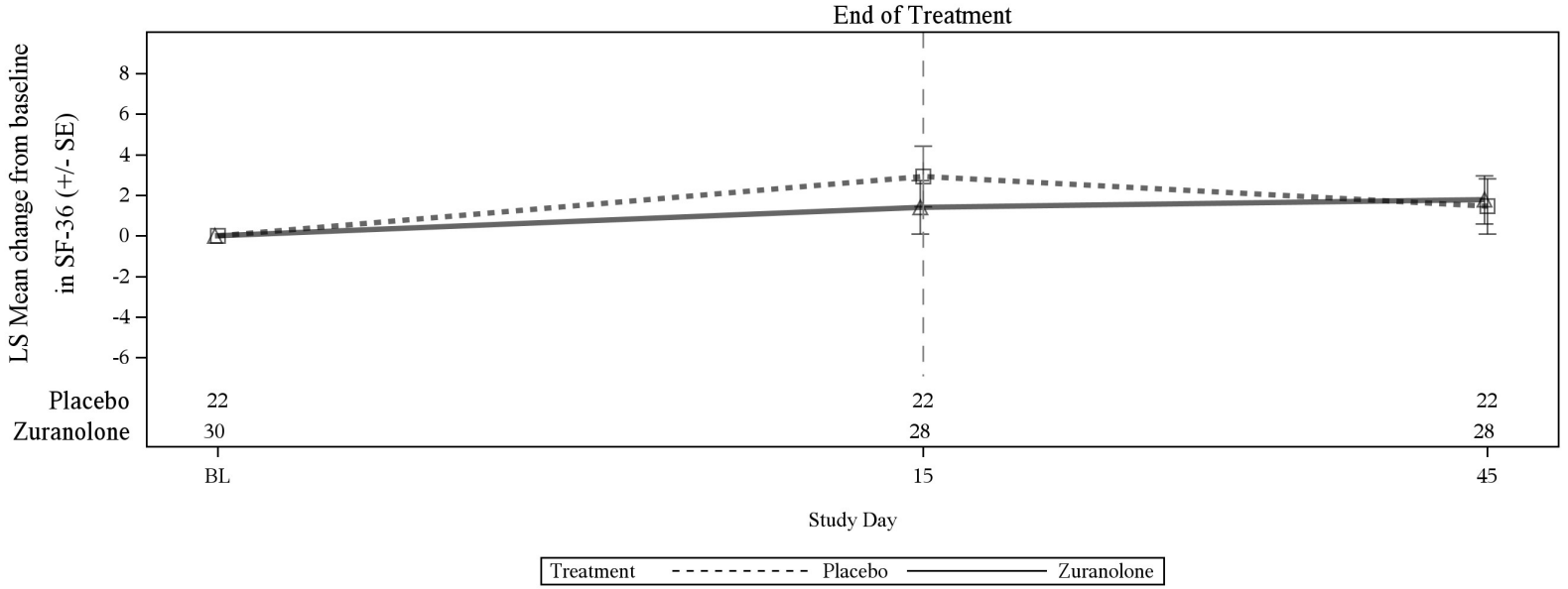
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Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

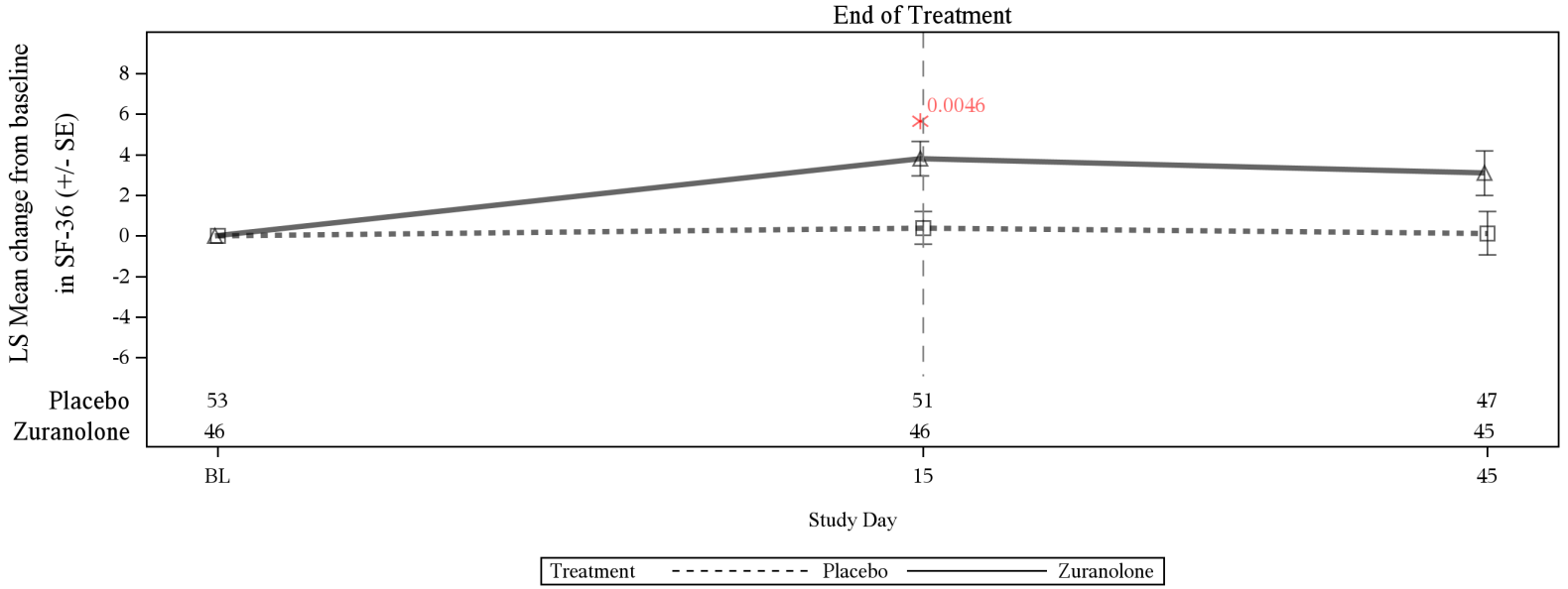
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Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

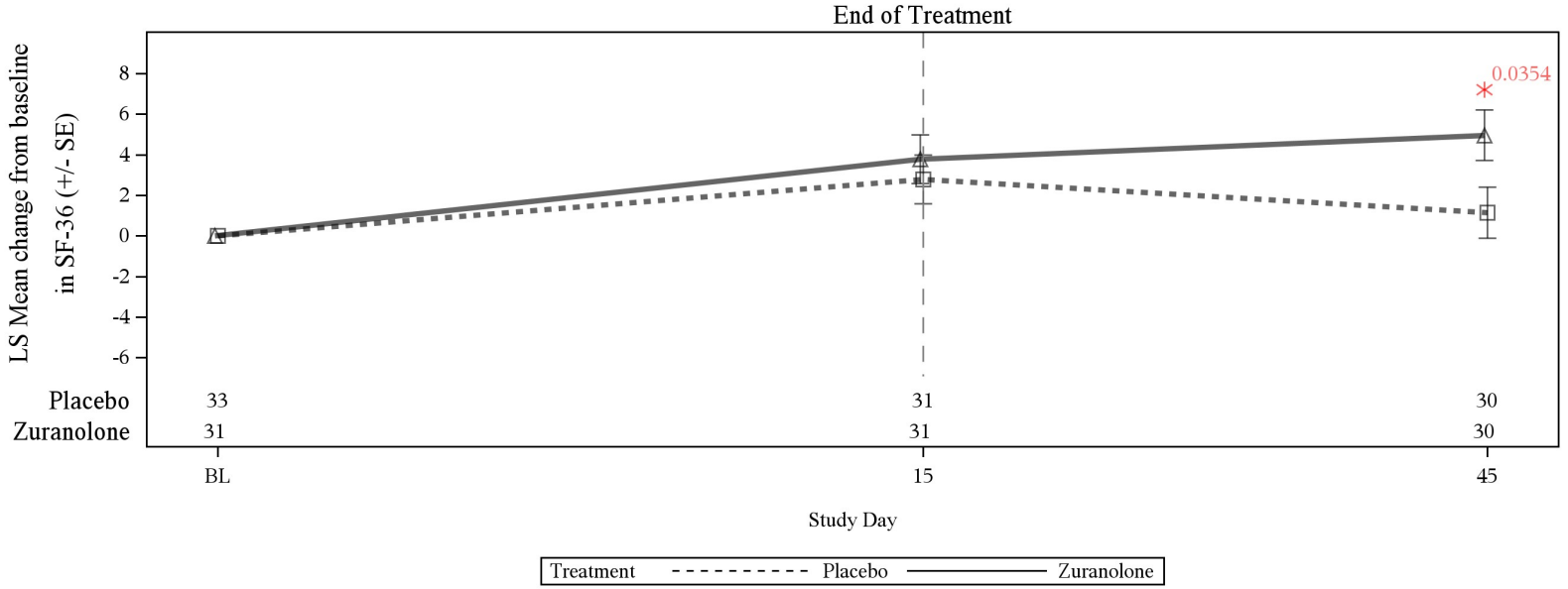
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Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

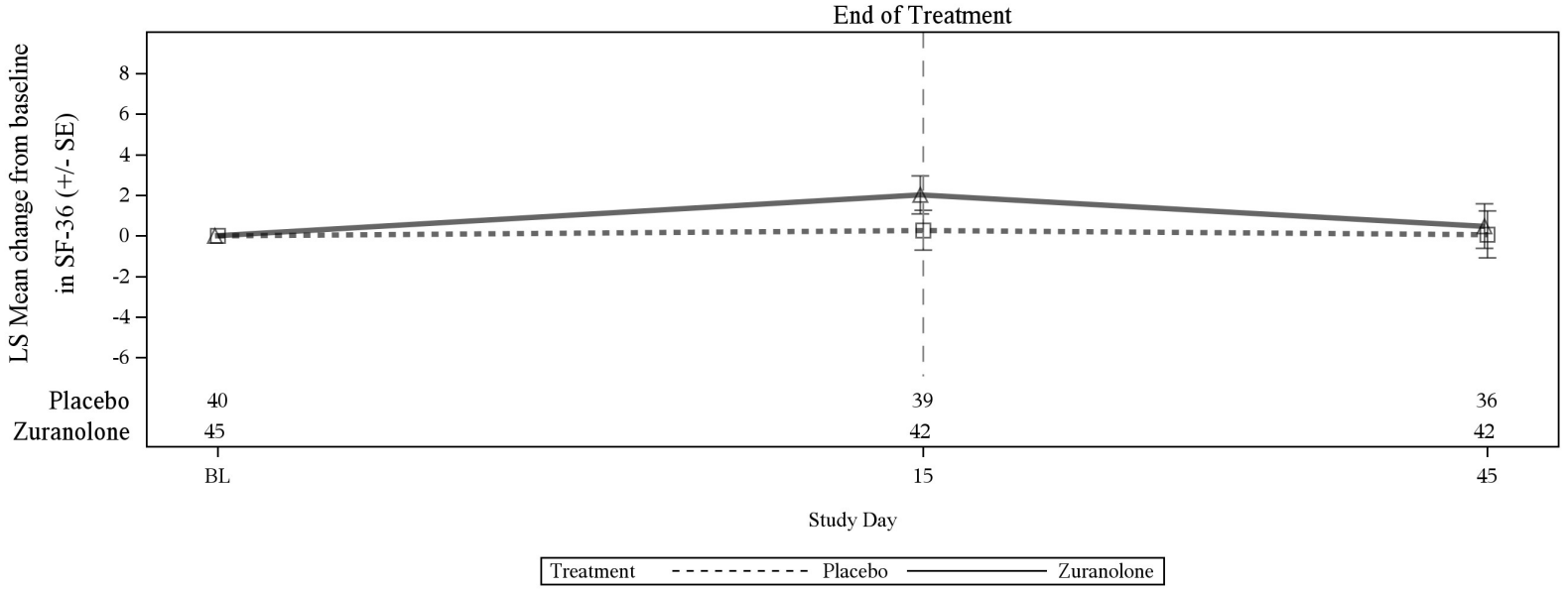
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Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

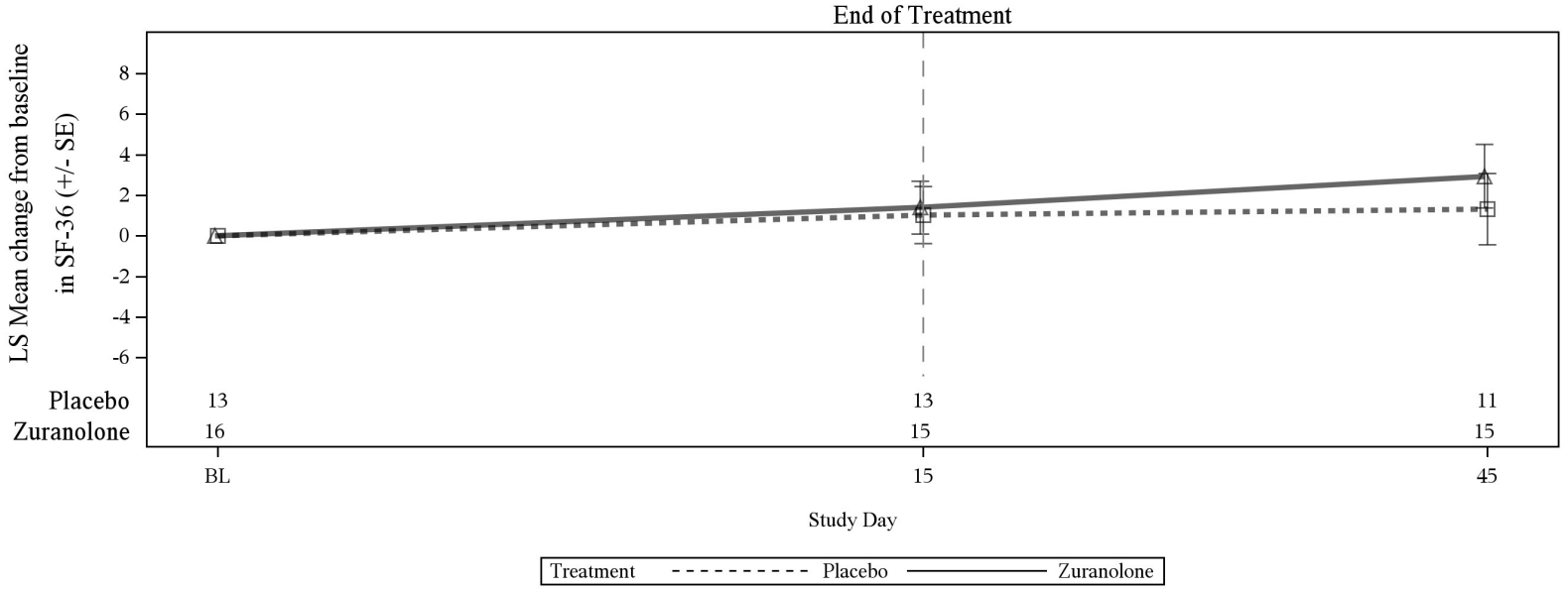
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 7 of 17

Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

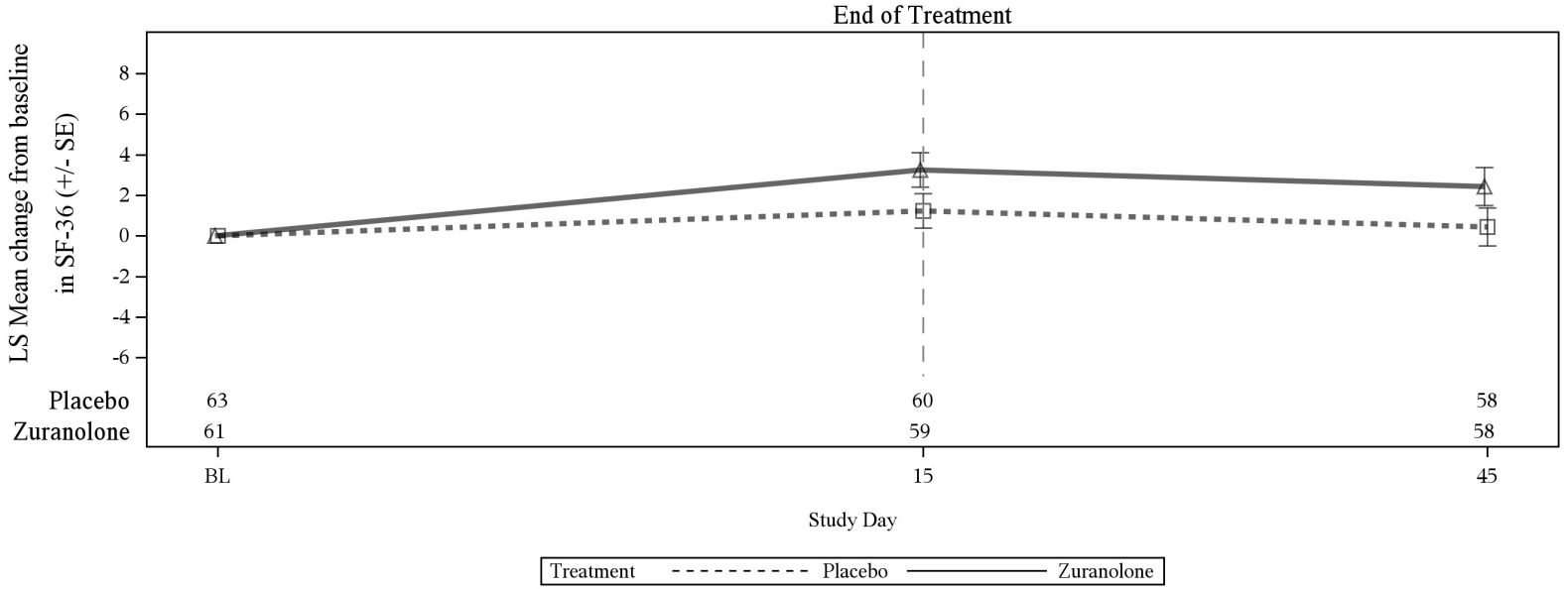
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Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

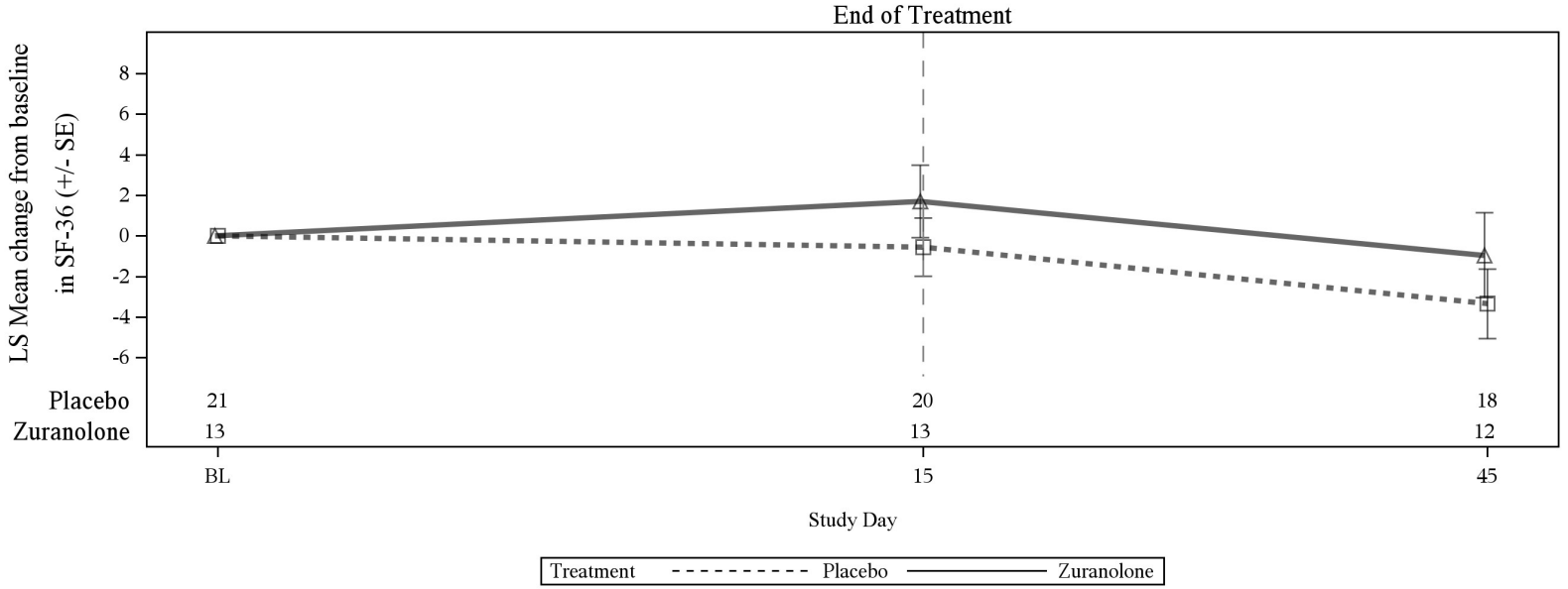
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Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

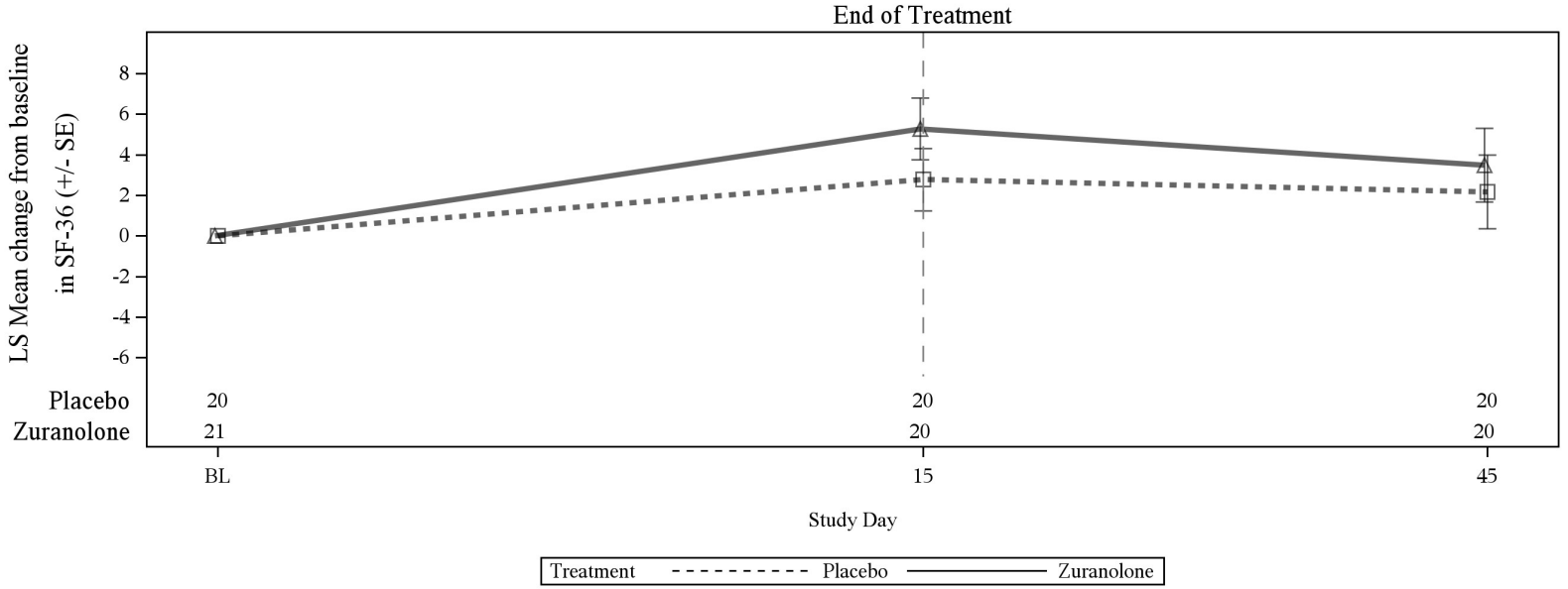
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

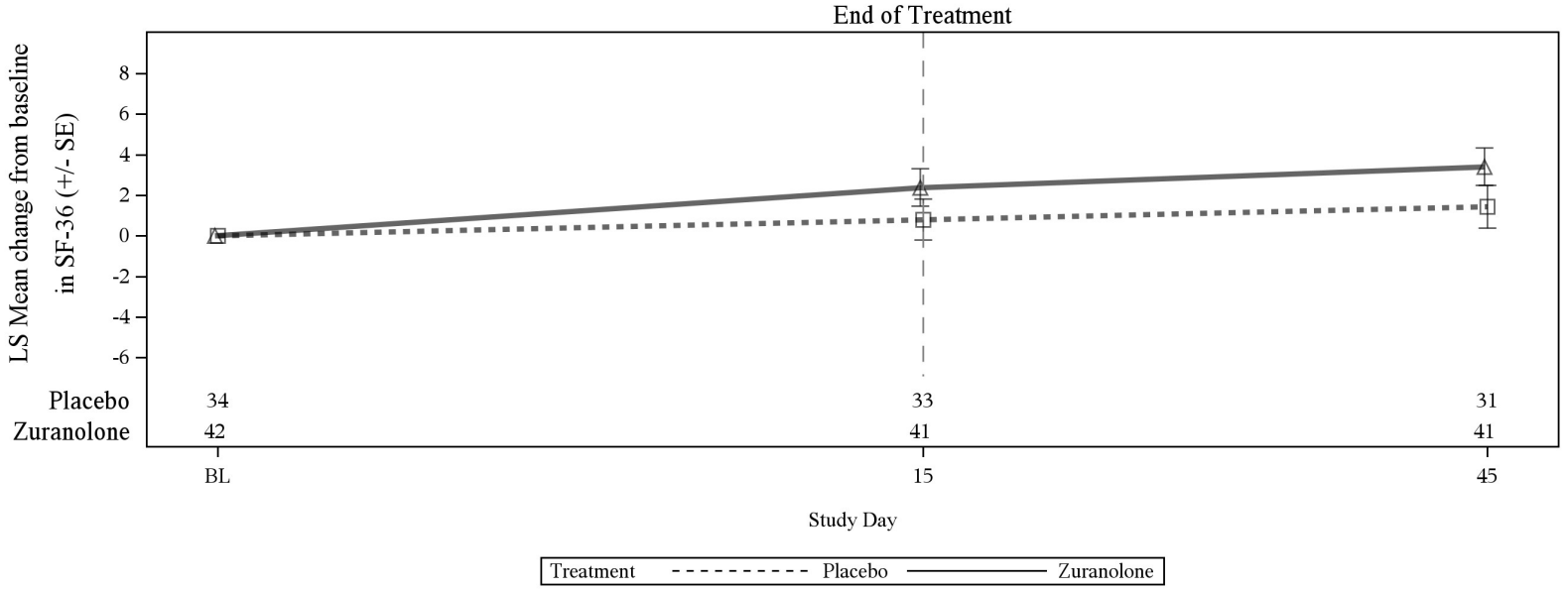
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

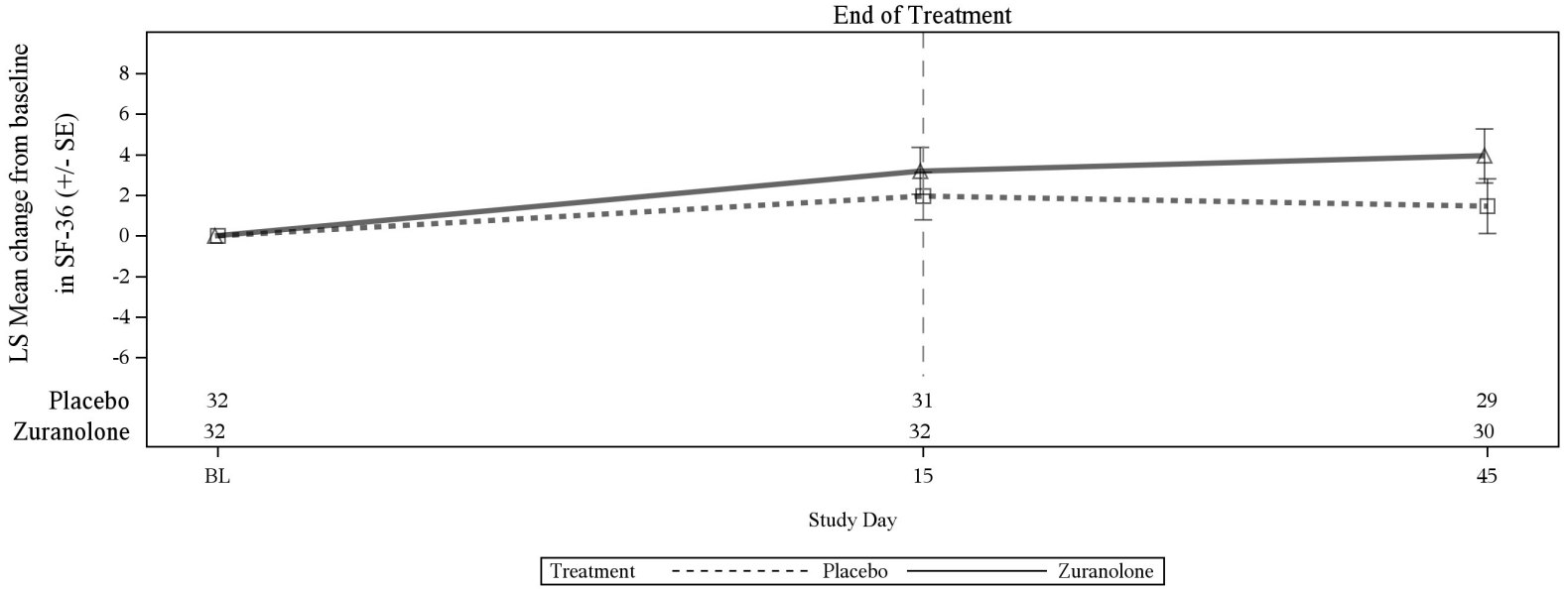
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

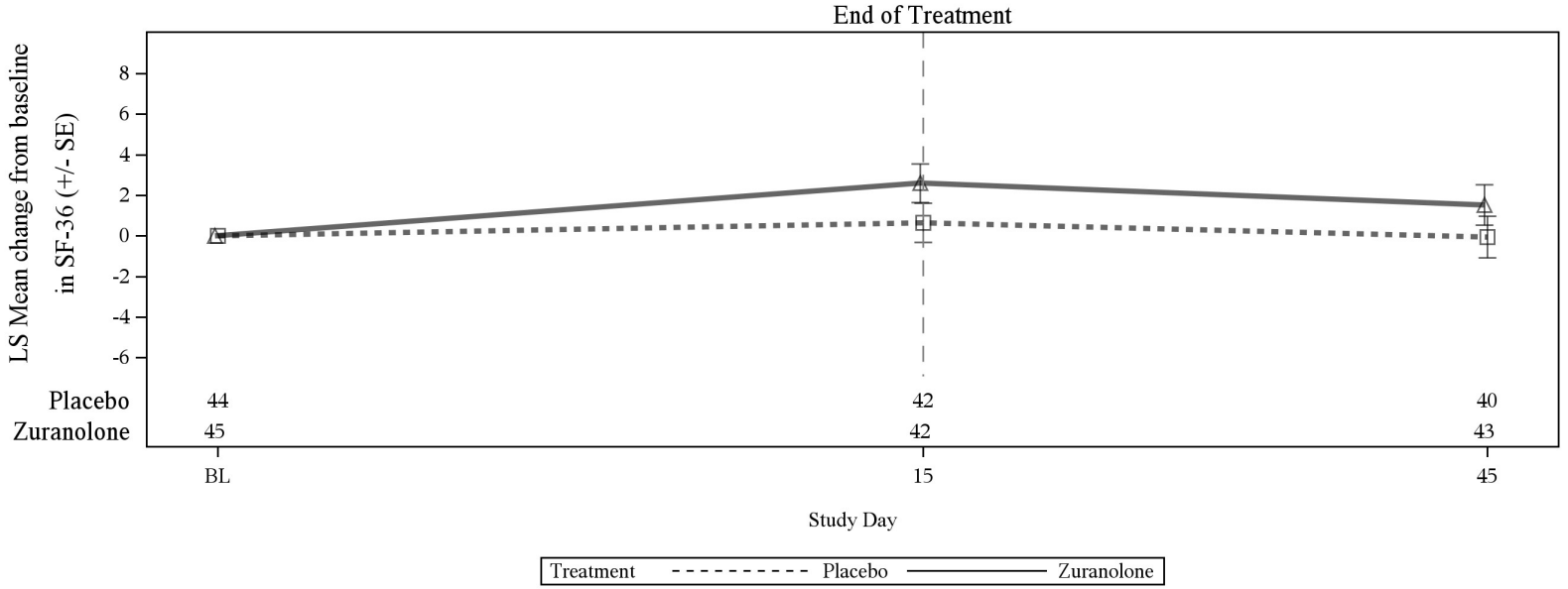
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

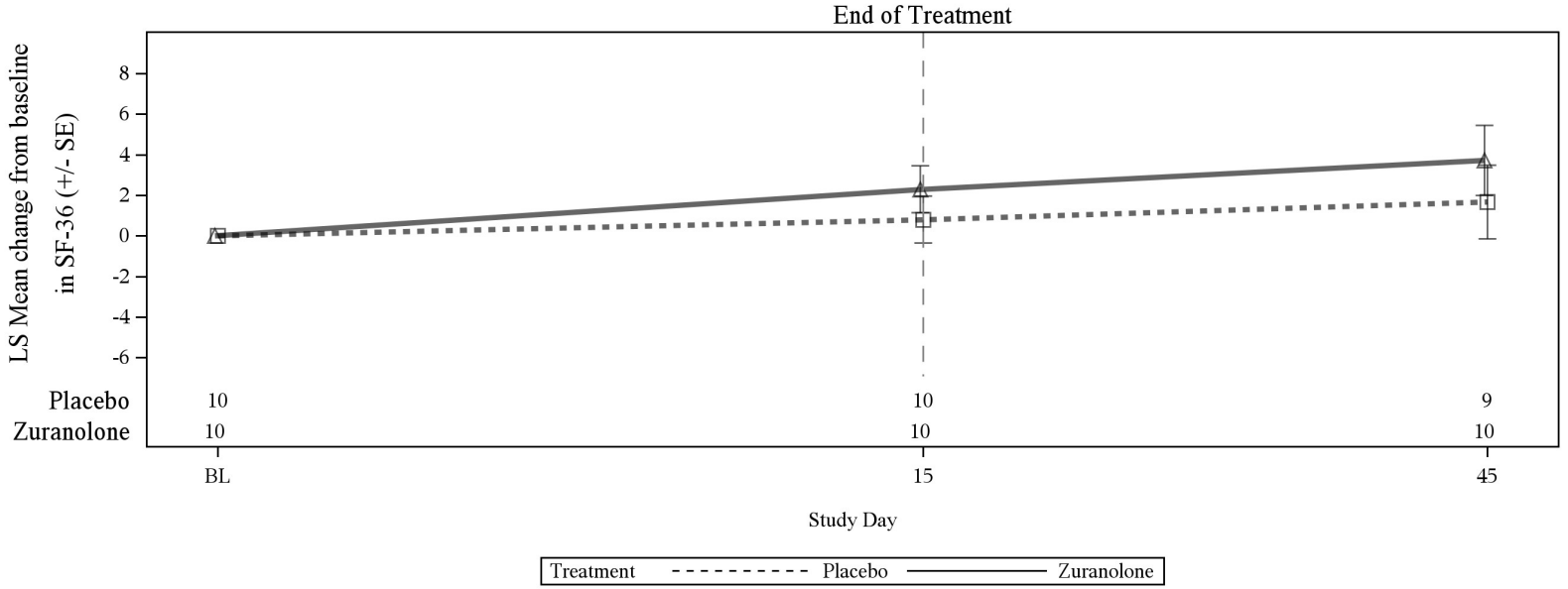
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

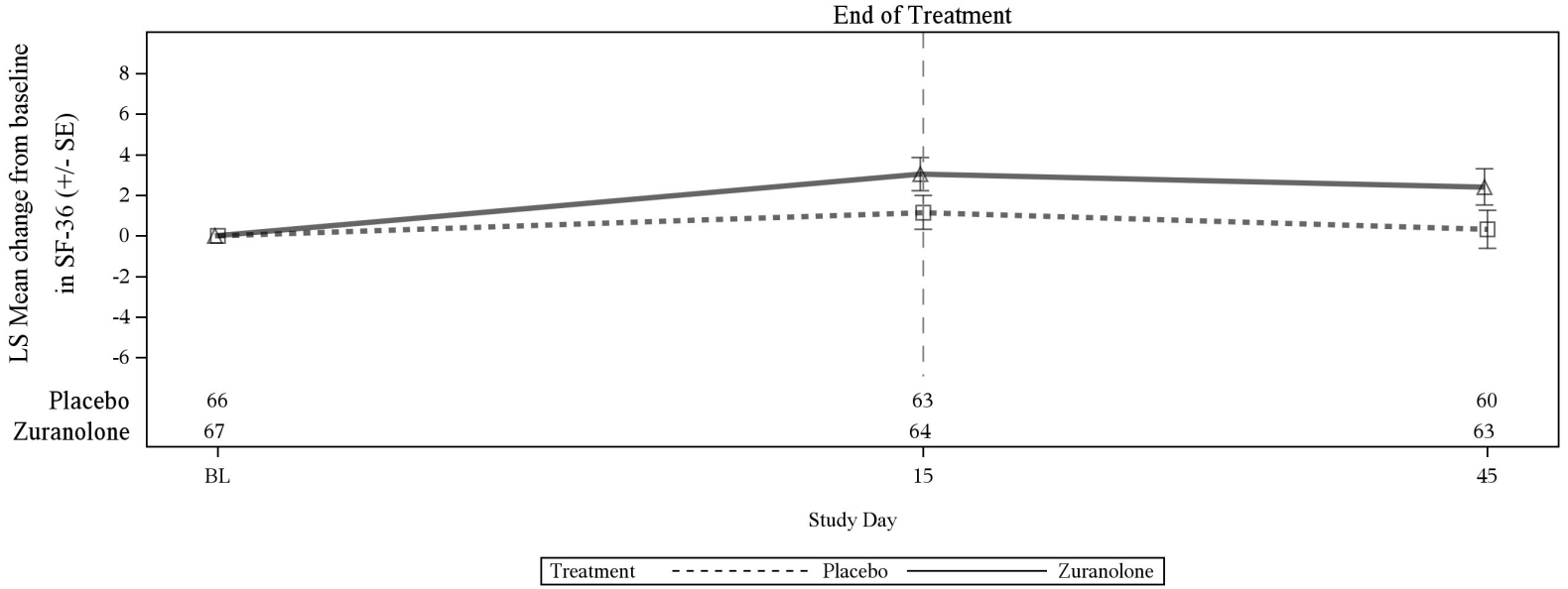
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

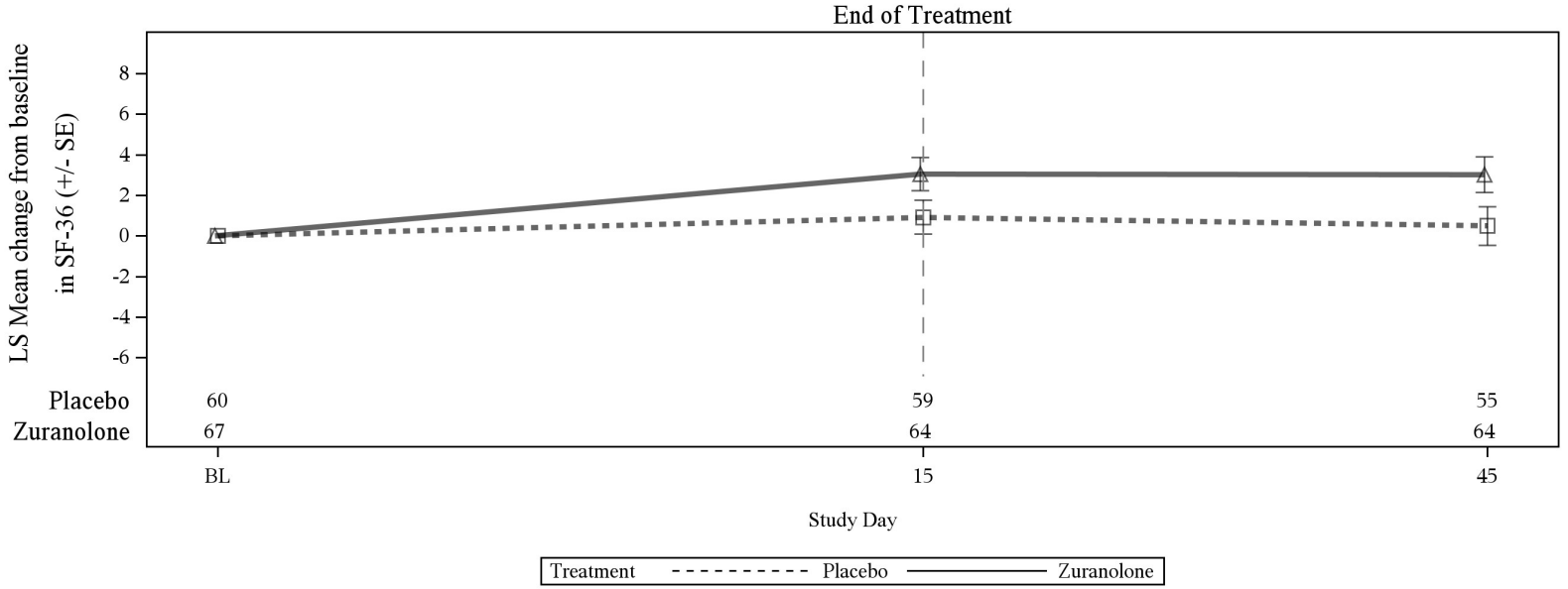
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

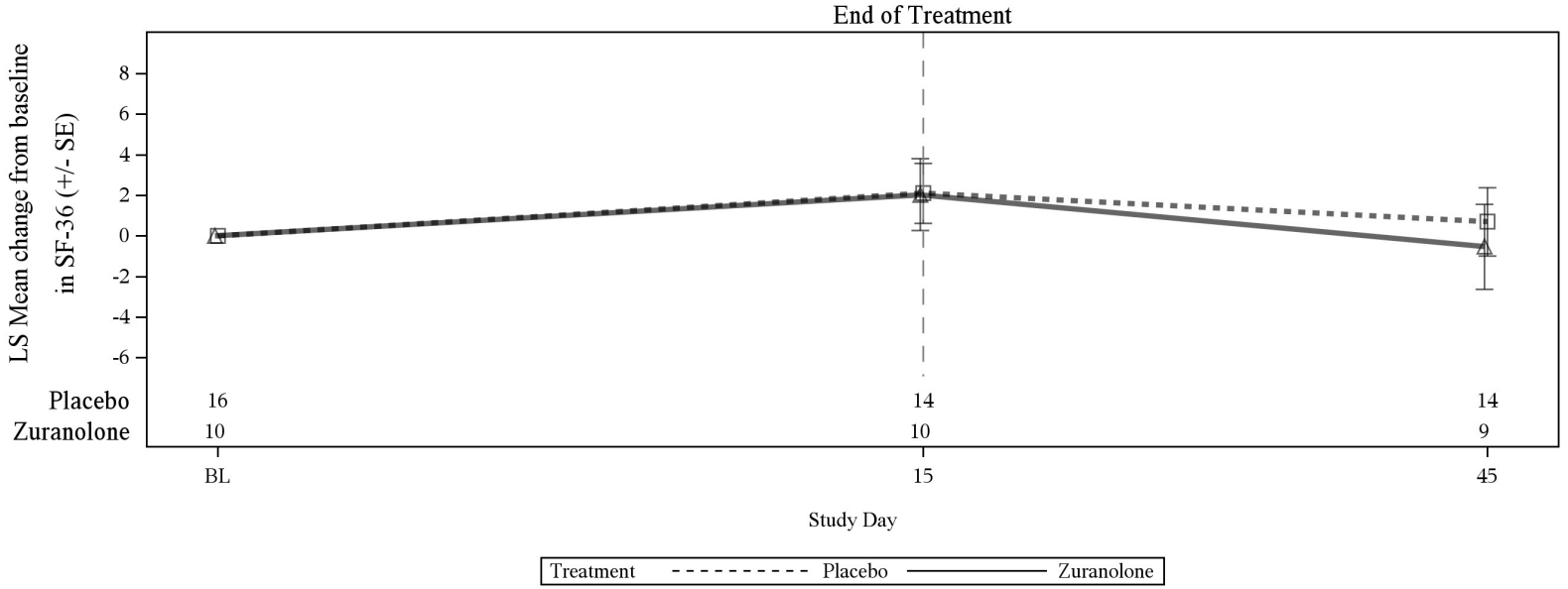
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Component Summary by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-phys-mmrm-201-by.sas:f-sf36-phys-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

2.2.2 Ansprechen

2.2.2.1 Responder-Analysen

2.2.2.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with a response, n (%) [2]	9 (12.0)	15 (19.7)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.500
95% CI for the RR		(0.718, 3.133)
p-value for RR		0.2802
OR - Odds Ratio (Zuranolone vs. Placebo)		1.670
95% CI for the OR		(0.646, 4.315)
p-value for OR		0.2899
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.
[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-ovr.sas:t-sf36-phys-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	7 (9.3)	12 (15.8)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.543
95% CI for the RR		(0.659, 3.615)
p-value for RR		0.3177
OR - Odds Ratio (Zuranolone vs. Placebo)		1.694
95% CI for the OR		(0.599, 4.791)
p-value for OR		0.3200
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-ovr.sas:t-sf36-phys-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.2.2.1 .2 Subgruppen

2.2.2.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	9 (12.0)	15 (19.7)	
Number of subjects with response at Day 45, n (%)	7 (9.3)	12 (15.8)	
Age Group (years)			0.8519
Day 15			
18 - 24, n / N (%)	3/25 (12.0)	5/17 (29.4)	
25 - 45, n / N (%)	6/50 (12.0)	10/59 (16.9)	
Day 45			
18 - 24, n / N (%)	2/25 (8.0)	3/17 (17.6)	
25 - 45, n / N (%)	5/50 (10.0)	9/59 (15.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-int.sas:t-sf36-phys-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.1583
Day 15			
<28, n / N (%)	3/22 (13.6)	5/30 (16.7)	
>=28, n / N (%)	6/53 (11.3)	10/46 (21.7)	
Day 45			
<28, n / N (%)	3/22 (13.6)	3/30 (10.0)	
>=28, n / N (%)	4/53 (7.5)	9/46 (19.6)	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	7/32 (21.9)	8/31 (25.8)	
White, n / N (%)	2/40 (5.0)	7/44 (15.9)	
Day 45			
Black or African American, n / N (%)	4/32 (12.5)	6/31 (19.4)	
White, n / N (%)	3/40 (7.5)	6/44 (13.6)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-int.sas:t-sf36-phys-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.8388
Day 15			
Yes, n / N (%)	1/13 (7.7)	1/16 (6.3)	
No, n / N (%)	8/62 (12.9)	14/60 (23.3)	
Day 45			
Yes, n / N (%)	1/13 (7.7)	3/16 (18.8)	
No, n / N (%)	6/62 (9.7)	9/60 (15.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-int.sas:t-sf36-phys-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	2/21 (9.5)	3/13 (23.1)	
25-29.9, n / N (%)	4/20 (20.0)	6/21 (28.6)	
>=30, n / N (%)	3/34 (8.8)	6/42 (14.3)	
Day 45			
<=24.9, n / N (%)	1/21 (4.8)	1/13 (7.7)	
25-29.9, n / N (%)	4/20 (20.0)	6/21 (28.6)	
>=30, n / N (%)	2/34 (5.9)	5/42 (11.9)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-int.sas:t-sf36-phys-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 5 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	5/32 (15.6)	6/32 (18.8)	
Postpartum, n / N (%)	4/43 (9.3)	9/44 (20.5)	
Day 45			
3rd Trimester, n / N (%)	4/32 (12.5)	7/32 (21.9)	
Postpartum, n / N (%)	3/43 (7.0)	5/44 (11.4)	
Family History of PPD			NE
Day 15			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	9/65 (13.8)	15/66 (22.7)	
Day 45			
Yes, n / N (%)	1/10 (10.0)	1/10 (10.0)	
No/Unknown, n / N (%)	6/65 (9.2)	11/66 (16.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-int.sas:t-sf36-phys-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NE
Day 15			
1st Episode, n / N (%)	6/59 (10.2)	15/66 (22.7)	
Recurrent Episode, n / N (%)	3/16 (18.8)	0/10	
Day 45			
1st Episode, n / N (%)	6/59 (10.2)	12/66 (18.2)	
Recurrent Episode, n / N (%)	1/16 (6.3)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/8	1/10 (10.0)	
>=20, n / N (%)	9/67 (13.4)	14/66 (21.2)	
Day 45			
<20, n / N (%)	0/8	2/10 (20.0)	
>=20, n / N (%)	7/67 (10.4)	10/66 (15.2)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-int.sas:t-sf36-phys-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

2.2.2.1 .2 .2 Subgruppenanalysen

2.2.2.1 .2 .2 .1 Alter

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 15		
Number of subjects with a response, n (%) [2]	3 (12.0)	5 (29.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.829
95% CI for the RR		(0.525, 6.366)
p-value for RR		0.3429
Day 45		
Number of subjects with a response, n (%) [2]	2 (8.0)	3 (17.6)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.646
95% CI for the RR		(0.307, 8.810)
p-value for RR		0.5605

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 15		
Number of subjects with a response, n (%) [2]	6 (12.0)	10 (16.9)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.421
95% CI for the RR		(0.586, 3.449)
p-value for RR		0.4372
Day 45		
Number of subjects with a response, n (%) [2]	5 (10.0)	9 (15.3)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.535
95% CI for the RR		(0.588, 4.005)
p-value for RR		0.3814

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.2.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 15		
Number of subjects with a response, n (%) [2]	3 (13.6)	5 (16.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.031
95% CI for the RR		(0.255, 4.175)
p-value for RR		0.9654
Day 45		
Number of subjects with a response, n (%) [2]	3 (13.6)	3 (10.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.619
95% CI for the RR		(0.133, 2.873)
p-value for RR		0.5401

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 15		
Number of subjects with a response, n (%) [2]	6 (11.3)	10 (21.7)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.010
95% CI for the RR		(0.858, 4.704)
p-value for RR		0.1078
Day 45		
Number of subjects with a response, n (%) [2]	4 (7.5)	9 (19.6)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.713
95% CI for the RR		(0.943, 7.801)
p-value for RR		0.0640

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.2.2.1 .2 .2 .3 Abstammung

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 15		
Number of subjects with a response, n (%) [2]	7 (21.9)	8 (25.8)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.18
95% CI for the RR		(0.486, 2.861)
p-value for RR		0.7146
Day 45		
Number of subjects with a response, n (%) [2]	4 (12.5)	6 (19.4)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.55
95% CI for the RR		(0.483, 4.963)
p-value for RR		0.4619

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 15		
Number of subjects with a response, n (%) [2]	2 (5.0)	7 (15.9)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		3.18
95% CI for the RR		(0.701, 14.432)
p-value for RR		0.1335
Day 45		
Number of subjects with a response, n (%) [2]	3 (7.5)	6 (13.6)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.82
95% CI for the RR		(0.487, 6.793)
p-value for RR		0.3740

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.2.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 15		
Number of subjects with a response, n (%) [2]	1 (7.7)	1 (6.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.596
95% CI for the RR		(0.039, 9.165)
p-value for RR		0.7108
Day 45		
Number of subjects with a response, n (%) [2]	1 (7.7)	3 (18.8)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.789
95% CI for the RR		(0.185, 17.312)
p-value for RR		0.6154

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 15		
Number of subjects with a response, n (%) [2]	8 (12.9)	14 (23.3)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.637
95% CI for the RR		(0.769, 3.486)
p-value for RR		0.2014
Day 45		
Number of subjects with a response, n (%) [2]	6 (9.7)	9 (15.0)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.403
95% CI for the RR		(0.553, 3.561)
p-value for RR		0.4763

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.2.2.1 .2 .2 .5 BMI

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 15		
Number of subjects with a response, n (%) [2]	2 (9.5)	3 (23.1)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.42
95% CI for the RR		(0.465, 12.618)
p-value for RR		0.2931
Day 45		
Number of subjects with a response, n (%) [2]	1 (4.8)	1 (7.7)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.62
95% CI for the RR		(0.110, 23.658)
p-value for RR		0.7262

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 15		
Number of subjects with a response, n (%) [2]	4 (20.0)	6 (28.6)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.43
95% CI for the RR		(0.472, 4.322)
p-value for RR		0.5277
Day 45		
Number of subjects with a response, n (%) [2]	4 (20.0)	6 (28.6)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.43
95% CI for the RR		(0.472, 4.322)
p-value for RR		0.5277

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 15		
Number of subjects with a response, n (%) [2]	3 (8.8)	6 (14.3)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.62
95% CI for the RR		(0.437, 6.001)
p-value for RR		0.4710
Day 45		
Number of subjects with a response, n (%) [2]	2 (5.9)	5 (11.9)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.02
95% CI for the RR		(0.418, 9.789)
p-value for RR		0.3807

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.2.2.1 .2 .2 .6 Beginn der PPD

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 15		
Number of subjects with a response, n (%) [2]	5 (15.6)	6 (18.8)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.136
95% CI for the RR		(0.410, 3.149)
p-value for RR		0.8060
Day 45		
Number of subjects with a response, n (%) [2]	4 (12.5)	7 (21.9)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.657
95% CI for the RR		(0.572, 4.802)
p-value for RR		0.3523

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 15		
Number of subjects with a response, n (%) [2]	4 (9.3)	9 (20.5)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		2.086
95% CI for the RR		(0.715, 6.091)
p-value for RR		0.1785
Day 45		
Number of subjects with a response, n (%) [2]	3 (7.0)	5 (11.4)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.545
95% CI for the RR		(0.397, 6.017)
p-value for RR		0.5302

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.2.2.1 .2 .2 .7 PPD in der Familie

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 15		
Number of subjects with a response, n (%) [2]	0	0
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		NE
95% CI for the RR		NE
p-value for RR		NE
Day 45		
Number of subjects with a response, n (%) [2]	1 (10.0)	1 (10.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.072, 13.868)
p-value for RR		1.0000

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 15		
Number of subjects with a response, n (%) [2]	9 (13.8)	15 (22.7)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.64
95% CI for the RR		(0.774, 3.482)
p-value for RR		0.1965
Day 45		
Number of subjects with a response, n (%) [2]	6 (9.2)	11 (16.7)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.81
95% CI for the RR		(0.710, 4.594)
p-value for RR		0.2150

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.2.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 15		
Number of subjects with a response, n (%) [2]	6 (10.2)	15 (22.7)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.23
95% CI for the RR		(0.928, 5.384)
p-value for RR		0.0730
Day 45		
Number of subjects with a response, n (%) [2]	6 (10.2)	12 (18.2)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.79
95% CI for the RR		(0.716, 4.464)
p-value for RR		0.2132

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 15		
Number of subjects with a response, n (%) [2]	3 (18.8)	0
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.22
95% CI for the RR		(0.013, 3.872)
p-value for RR		0.3013
Day 45		
Number of subjects with a response, n (%) [2]	1 (6.3)	0
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.52
95% CI for the RR		(0.023, 11.544)
p-value for RR		0.6759

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response (9.4 points (15% of total scale range) or greater increase in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

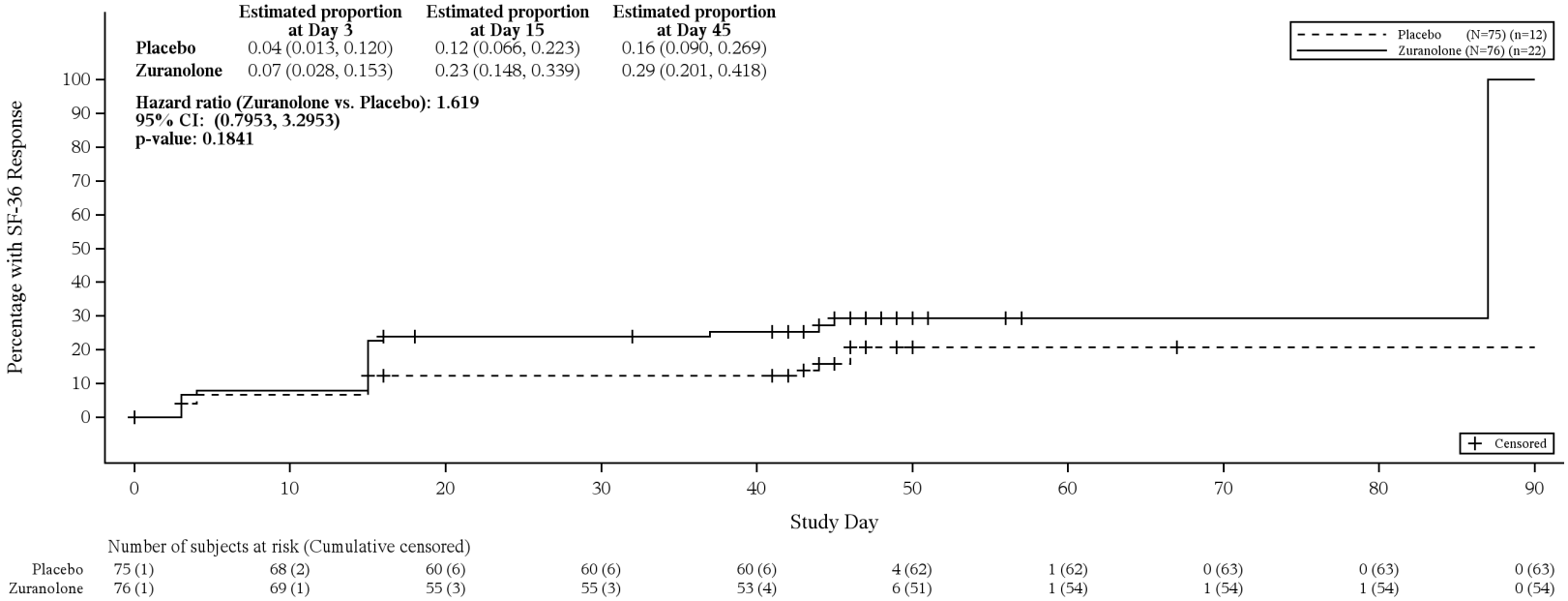
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-201-by.sas:t-sf36-phys-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.2.2.2 TTE-Analysen

2.2.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-ovr.sas:f-sf36-phys-resp15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	12 (16.0)	22 (28.9)
Time to first SF-36 Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (44.0, NE)	37.0 (15.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	87.0 (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.619
95% CI for the HR		(0.7953 , 3.2953)
p-value for the HR		0.1841

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-ovr.sas:t-sf36-phys-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.2.2.2 .2 Subgruppen

2.2.2.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	12 (16.0)	22 (28.9)	
Age Group (years)			
18 - 24, n / N (%)	4/25 (16.0)	7/17 (41.2)	0.9839
25 - 45, n / N (%)	8/50 (16.0)	15/59 (25.4)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	4/22 (18.2)	8/30 (26.7)	0.5115
>=28, n / N (%)	8/53 (15.1)	14/46 (30.4)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	9/32 (28.1)	11/31 (35.5)	0.2240
White, n / N (%)	3/40 (7.5)	11/44 (25.0)	
Antidepressant Use at Baseline			
Yes, n / N (%)	1/13 (7.7)	3/16 (18.8)	0.7428
No, n / N (%)	11/62 (17.7)	19/60 (31.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-int.sas:t-sf36-phys-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	3/21 (14.3)	3/13 (23.1)	0.5053(a)
25-29.9, n / N (%)	6/20 (30.0)	7/21 (33.3)	0.7792(b)
>=30, n / N (%)	3/34 (8.8)	12/42 (28.6)	0.2644(c)
Onset of PPD			
3rd Trimester, n / N (%)	6/32 (18.8)	11/32 (34.4)	0.7856
Postpartum, n / N (%)	6/43 (14.0)	11/44 (25.0)	
Family History of PPD			
Yes, n / N (%)	1/10 (10.0)	1/10 (10.0)	0.6010
No/Unknown, n / N (%)	11/65 (16.9)	21/66 (31.8)	
History of PPD			
1st Episode, n / N (%)	9/59 (15.3)	22/66 (33.3)	0.9905
Recurrent Episode, n / N (%)	3/16 (18.8)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/8	3/10 (30.0)	NA
>=20, n / N (%)	12/67 (17.9)	19/66 (28.8)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-int.sas:t-sf36-phys-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.2.2.2 .2 .2 Subgruppenanalysen

2.2.2.2 .2 .2 .1 Alter

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	4 (16.0)	7 (41.2)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (3.0, NE)	15.0 (3.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	87.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.607
95% CI for the HR		(0.4434 , 5.8243)
p-value for the HR		0.4702

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	8 (16.0)	15 (25.4)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (15.0, NE)	45.0 (15.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.620
95% CI for the HR		(0.6861 , 3.8229)
p-value for the HR		0.2712

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.2.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	4 (18.2)	8 (26.7)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	46.0 (3.0, NE)	15.0 (3.0, NE)
50th percentile - median (95% CI)	NE (46.0, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.291
95% CI for the HR		(0.3766 , 4.4261)
p-value for the HR		0.6844

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	8 (15.1)	14 (30.4)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (43.0, NE)	44.0 (15.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	87.0 (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.929
95% CI for the HR		(0.7976 , 4.6629)
p-value for the HR		0.1449

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.2.2.2 .2 .2 .3 Abstammung

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	9 (28.1)	11 (35.5)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	43.0 (4.0, NE)	15.0 (4.0, NE)
50th percentile - median (95% CI)	NE (44.0, NE)	87.0 (45.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.029
95% CI for the HR		(0.4145 , 2.5549)
p-value for the HR		0.9508

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	3 (7.5)	11 (25.0)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (46.0, NE)	44.0 (15.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.557
95% CI for the HR		(0.6918 , 9.4499)
p-value for the HR		0.1593

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.2.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	1 (7.7)	3 (18.8)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (3.0, NE)	NE (15.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (44.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.234
95% CI for the HR		(0.2310 , 21.6037)
p-value for the HR		0.4875

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 Physical Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	11 (17.7)	19 (31.7)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (43.0, NE)	15.0 (15.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	87.0 (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.542
95% CI for the HR		(0.7270 , 3.2704)
p-value for the HR		0.2590

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 Physical Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.2.2.2 .2 .2 .5 BMI

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	3 (14.3)	3 (23.1)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (15.0, NE)	NE (15.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.588
95% CI for the HR		(0.4843 , 13.8340)
p-value for the HR		0.2661

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	6 (30.0)	7 (33.3)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	44.0 (3.0, NE)	16.0 (3.0, NE)
50th percentile - median (95% CI)	NE (44.0, NE)	NE (16.0, NE)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.098
95% CI for the HR		(0.3653 , 3.3008)
p-value for the HR		0.8676

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	3 (8.8)	12 (28.6)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (15.0, NE)	44.0 (15.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	87.0 (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.732
95% CI for the HR		(0.7611 , 9.8073)
p-value for the HR		0.1232

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.2.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	6 (18.8)	11 (34.4)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (3.0, NE)	26.5 (3.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	87.0 (45.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.441
95% CI for the HR		(0.5181 , 4.0072)
p-value for the HR		0.4841

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	6 (14.0)	11 (25.0)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (43.0, NE)	44.0 (15.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.829
95% CI for the HR		(0.6709 , 4.9868)
p-value for the HR		0.2380

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.2.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	1 (10.0)	1 (10.0)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (46.0, NE)	NE (44.0, NE)
50th percentile - median (95% CI)	NE (46.0, NE)	NE (44.0, NE)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		NA
95% CI for the HR		NA
p-value for the HR		NA

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.
NA: Not available due to non-convergence of the statistical model.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	11 (16.9)	21 (31.8)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (15.0, NE)	15.0 (15.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	87.0 (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.727
95% CI for the HR		(0.8268 , 3.6071)
p-value for the HR		0.1460

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.

NA: Not available due to non-convergence of the statistical model.

Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.2.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	9 (15.3)	22 (33.3)
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (44.0, NE)	15.0 (15.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	87.0 (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.019
95% CI for the HR		(0.9221 , 4.4212)
p-value for the HR		0.0789

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.
NA: Not available due to non-convergence of the statistical model.
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	3 (18.8)	0
Time to first Physical Component Summary response (days) [3]		
25th percentile - Q1 (95% CI)	NE (3.0, NE)	NE (NE, NE)
50th percentile - median (95% CI)	NE (15.0, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		NA
95% CI for the HR		NA
p-value for the HR		NA

NOTE 1: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.

NA: Not available due to non-convergence of the statistical model.

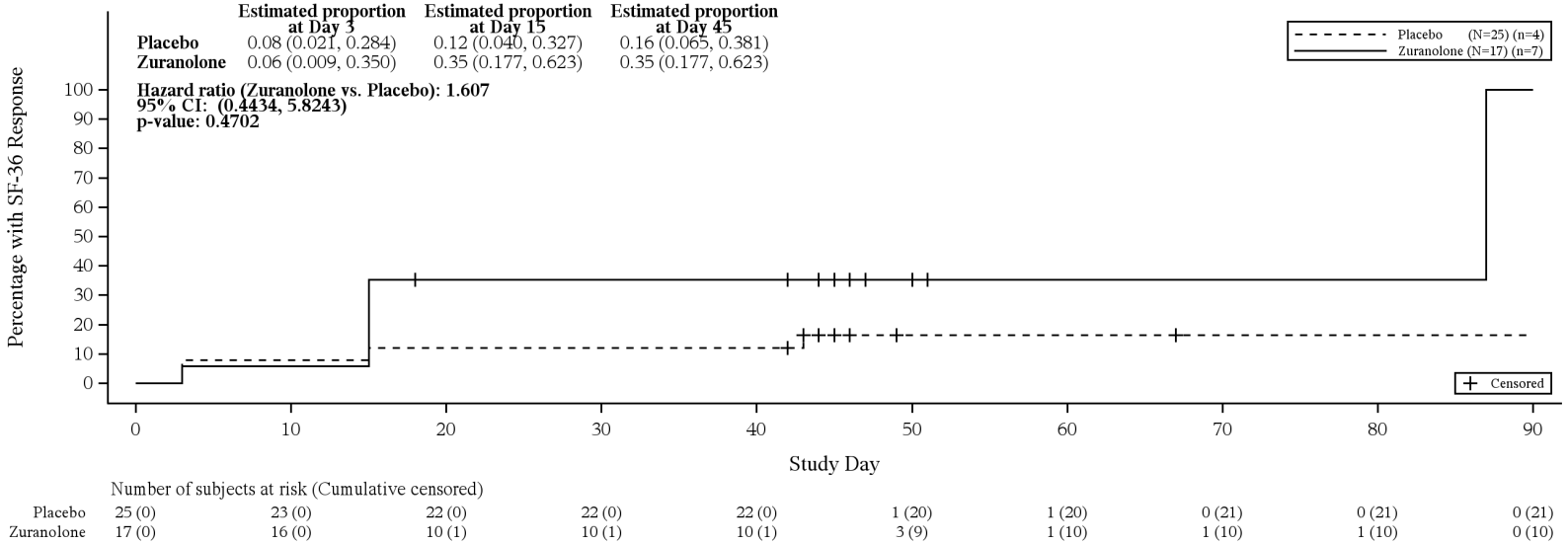
Source: biib125/v_a/germany_amnog/t-sf36-phys-resp15-tte-201-by.sas:t-sf36-phys-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.2.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

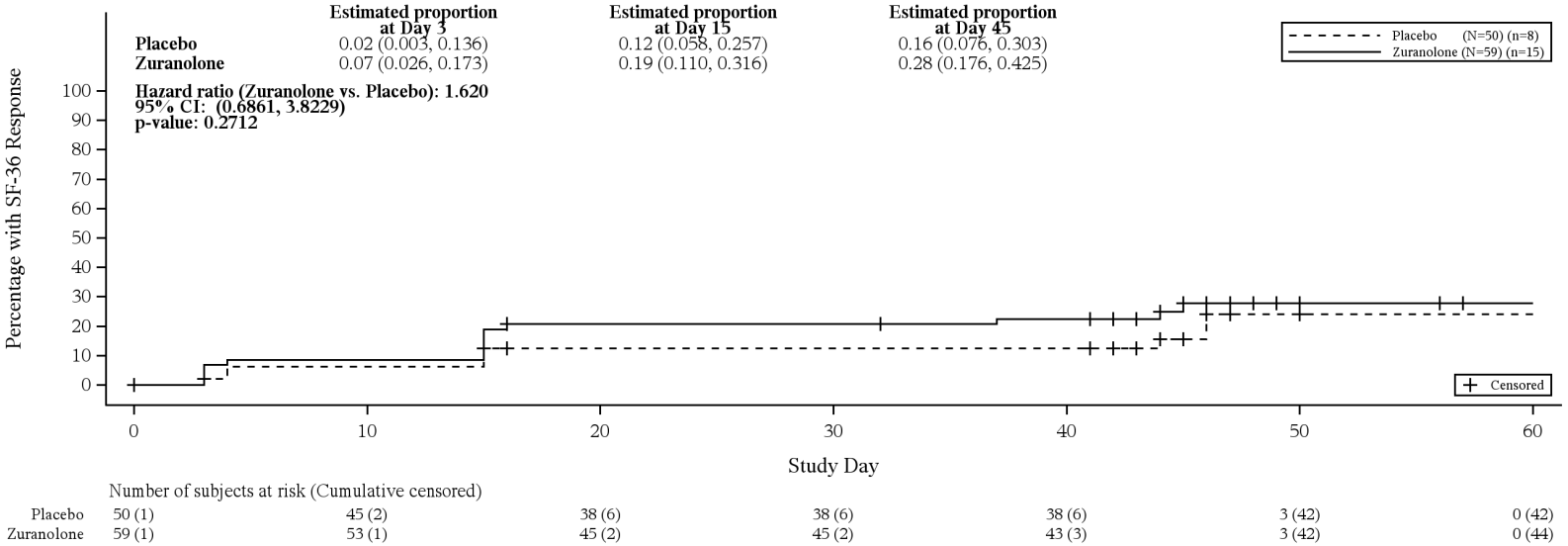


Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis. NA: Not available due to non-convergence of the statistical model.
Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

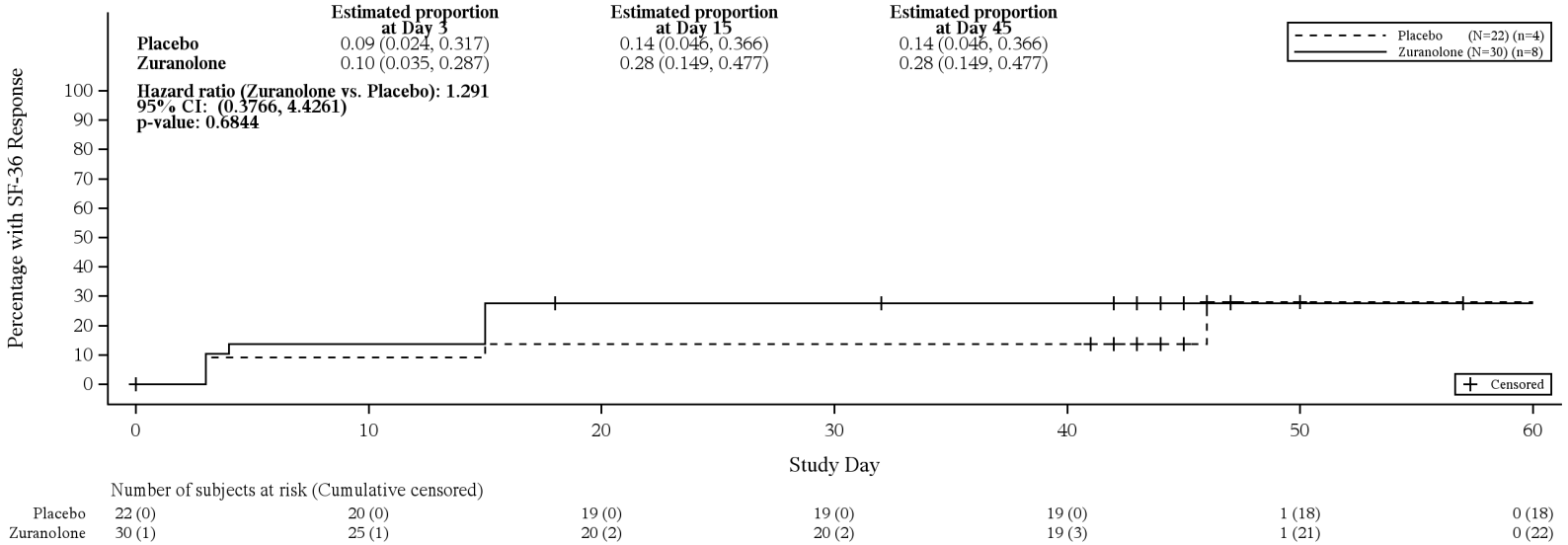
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis. NA: Not available due to non-convergence of the statistical model.

Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

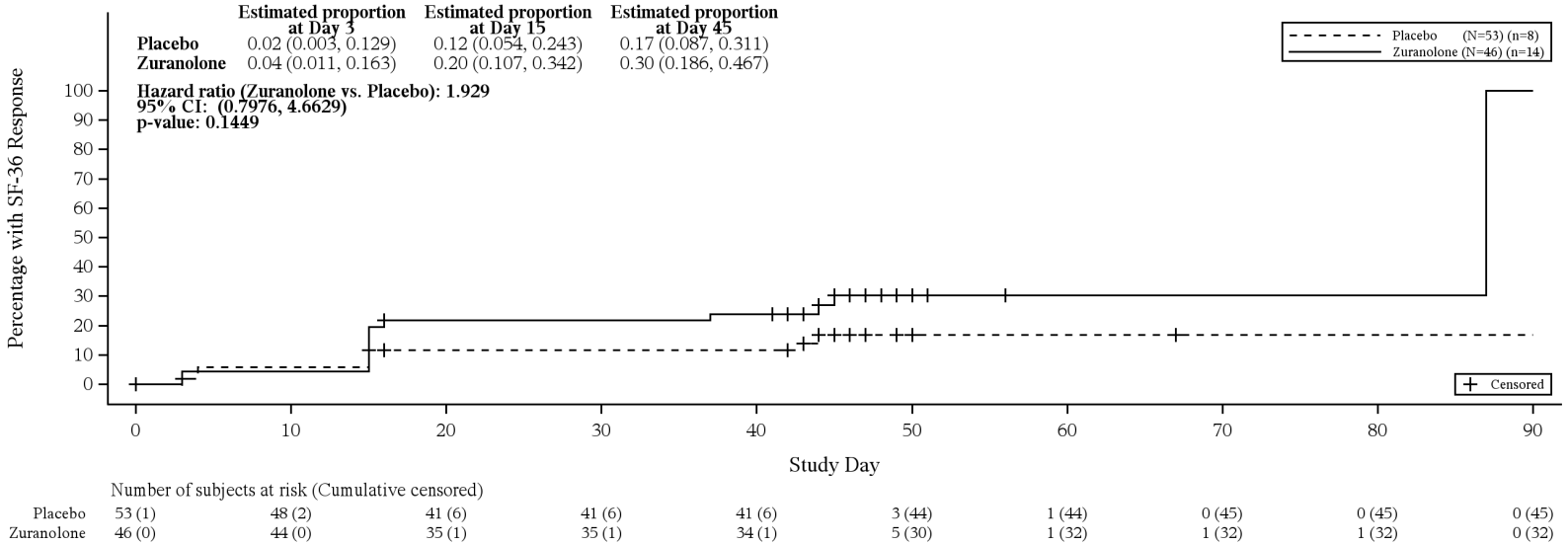
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis. NA: Not available due to non-convergence of the statistical model.

Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

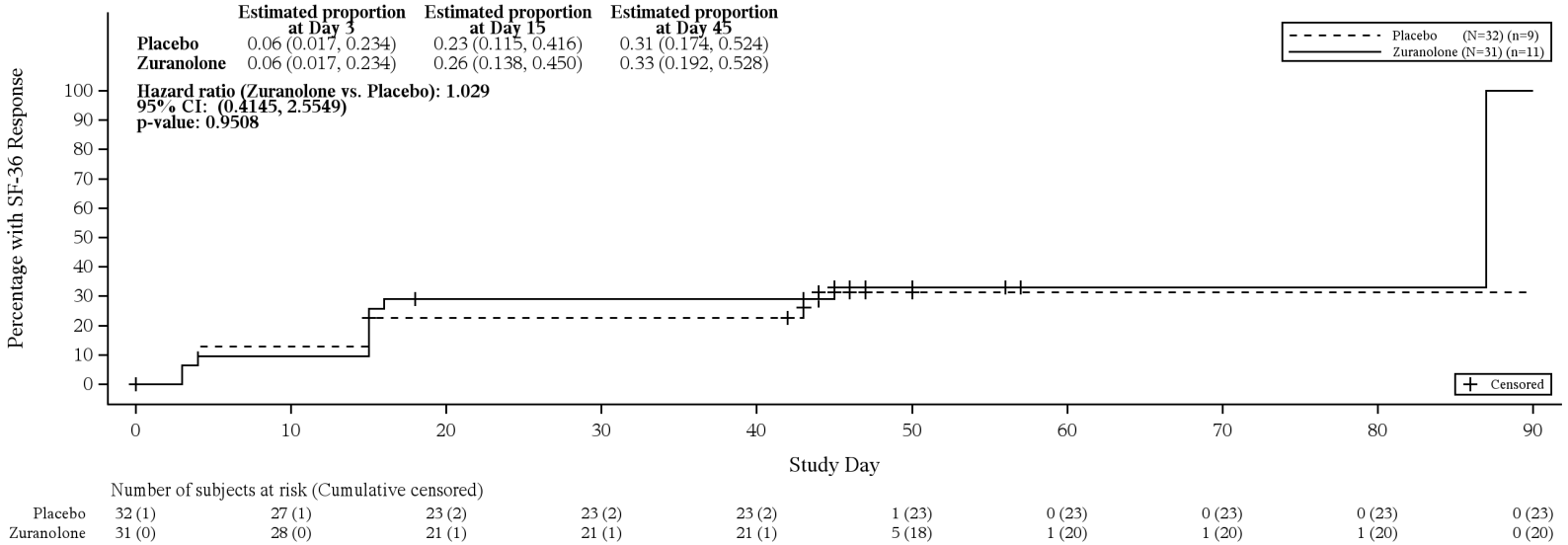
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis. NA: Not available due to non-convergence of the statistical model.

Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



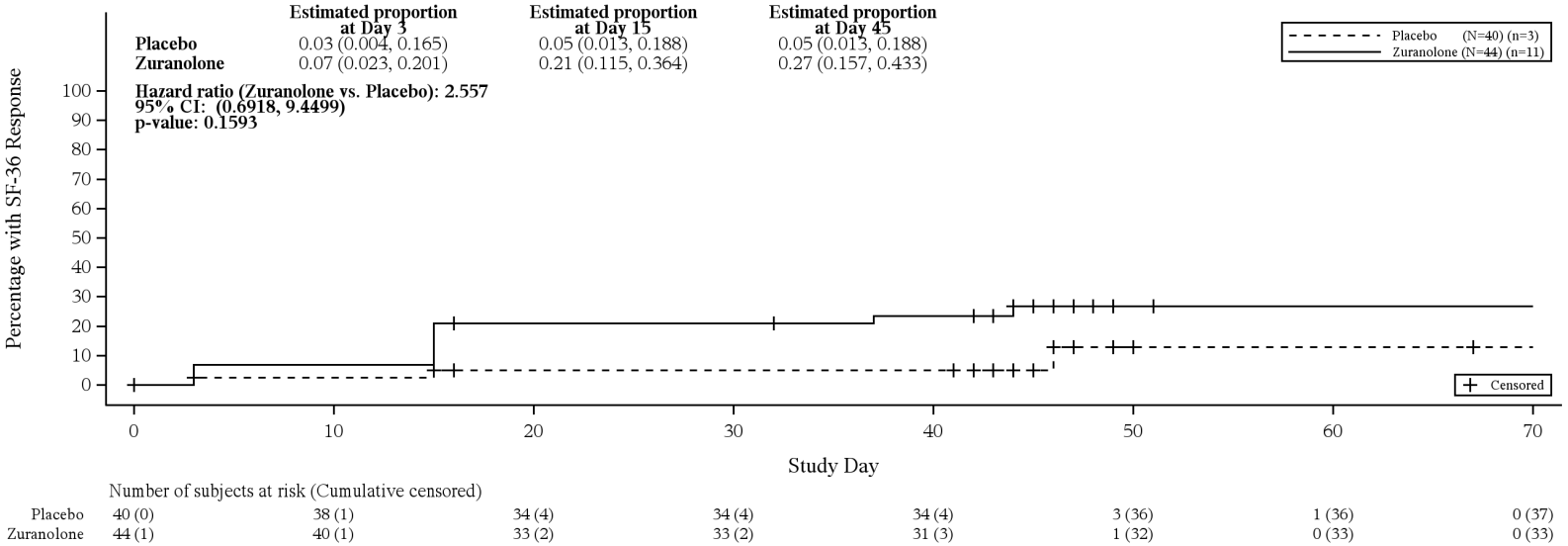
Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis. NA: Not available due to non-convergence of the statistical model.

Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



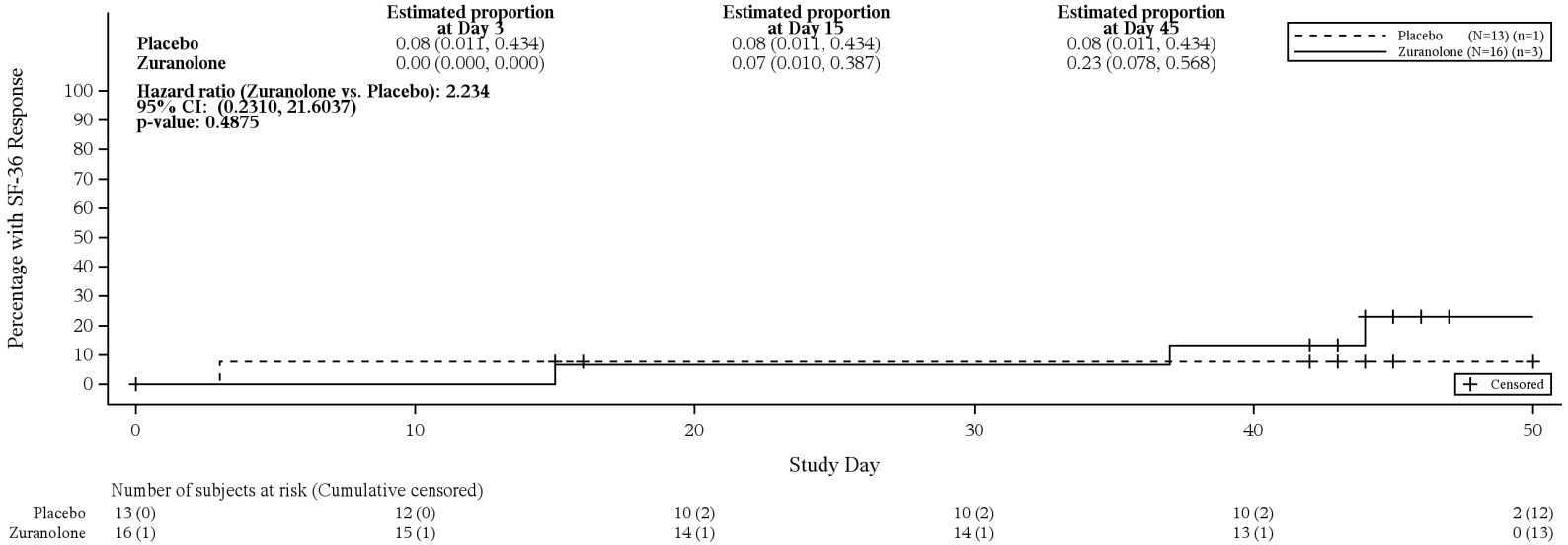
Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
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Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

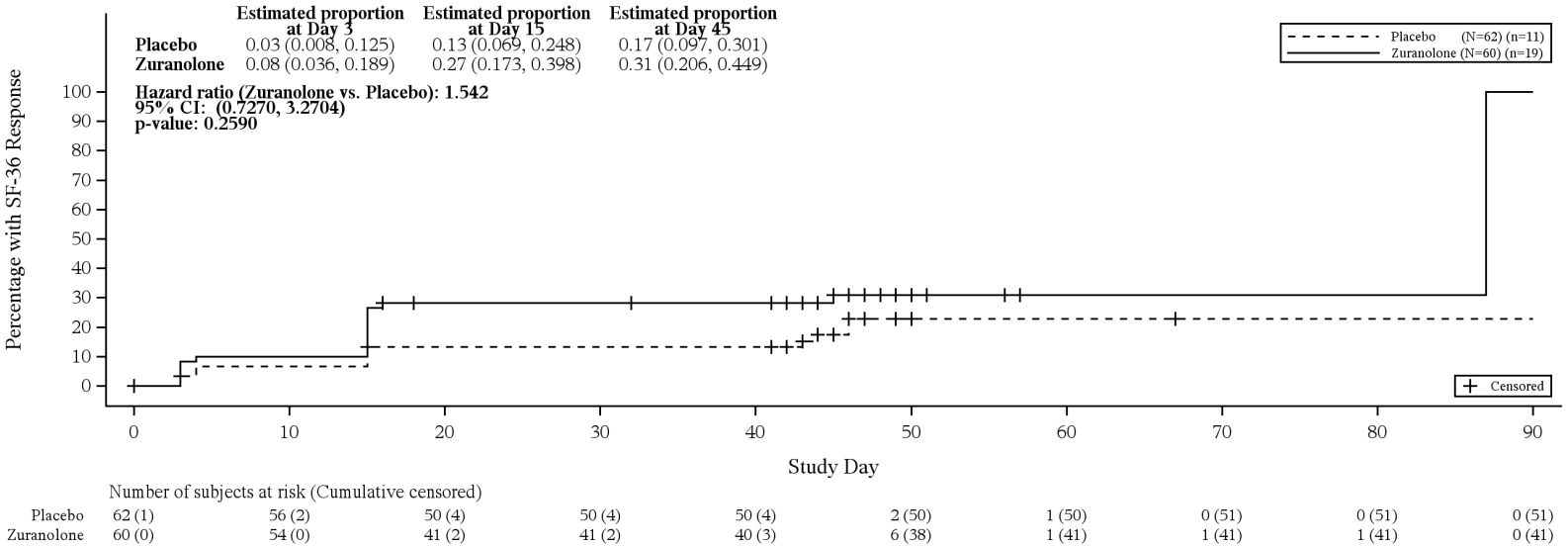
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Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

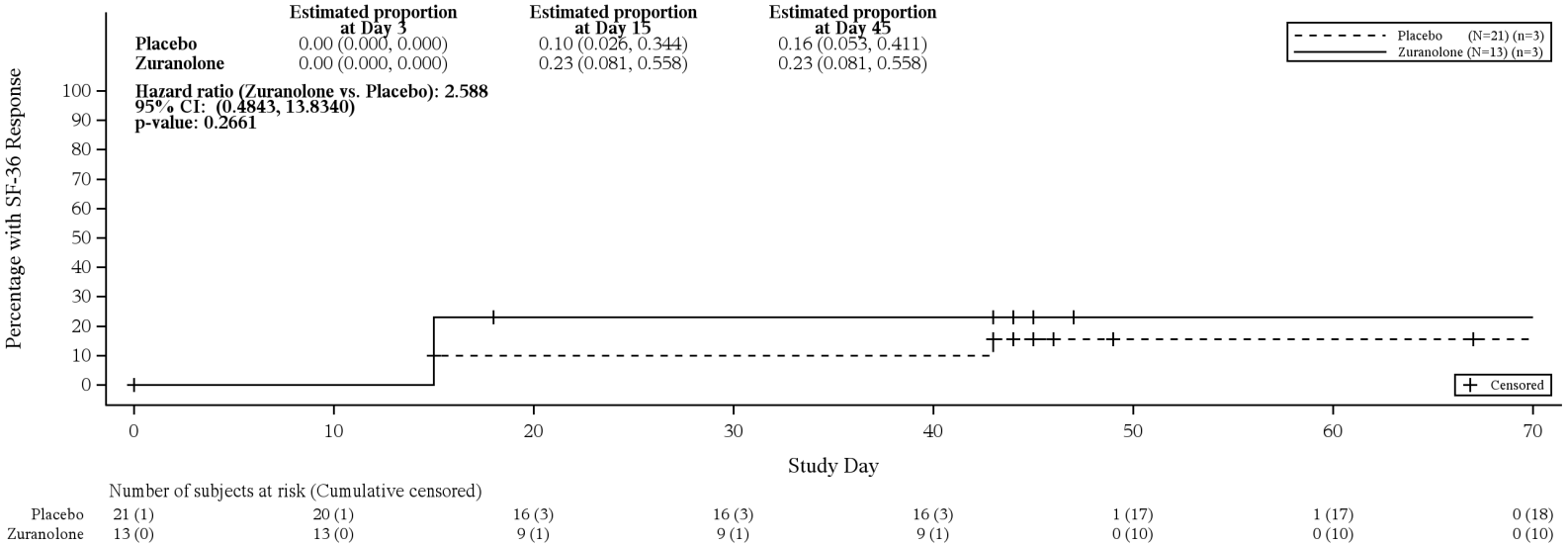
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis. NA: Not available due to non-convergence of the statistical model.

Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



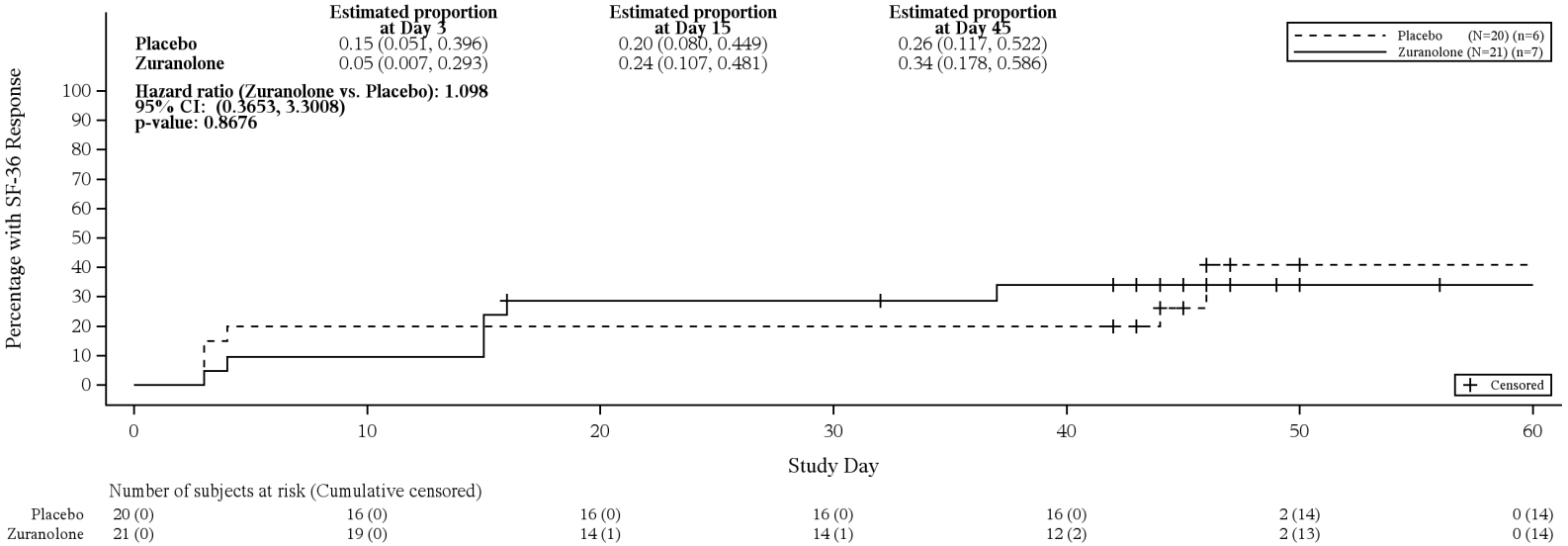
Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
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NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis. NA: Not available due to non-convergence of the statistical model.

Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

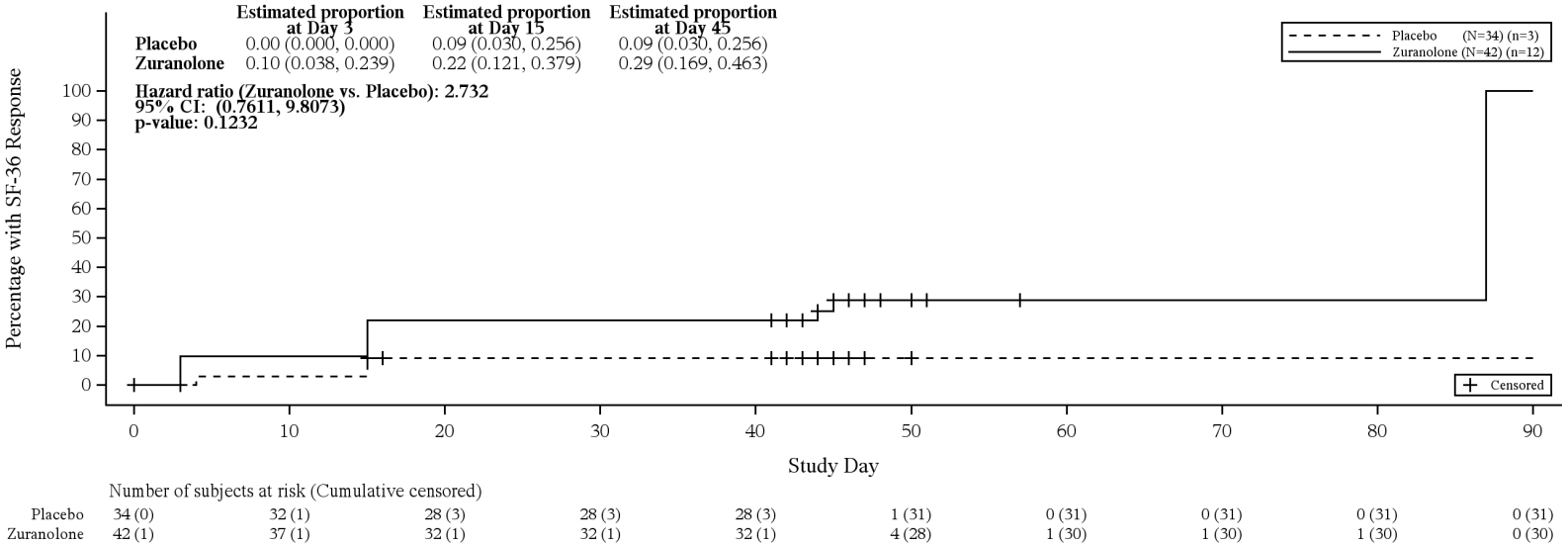
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis. NA: Not available due to non-convergence of the statistical model.

Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

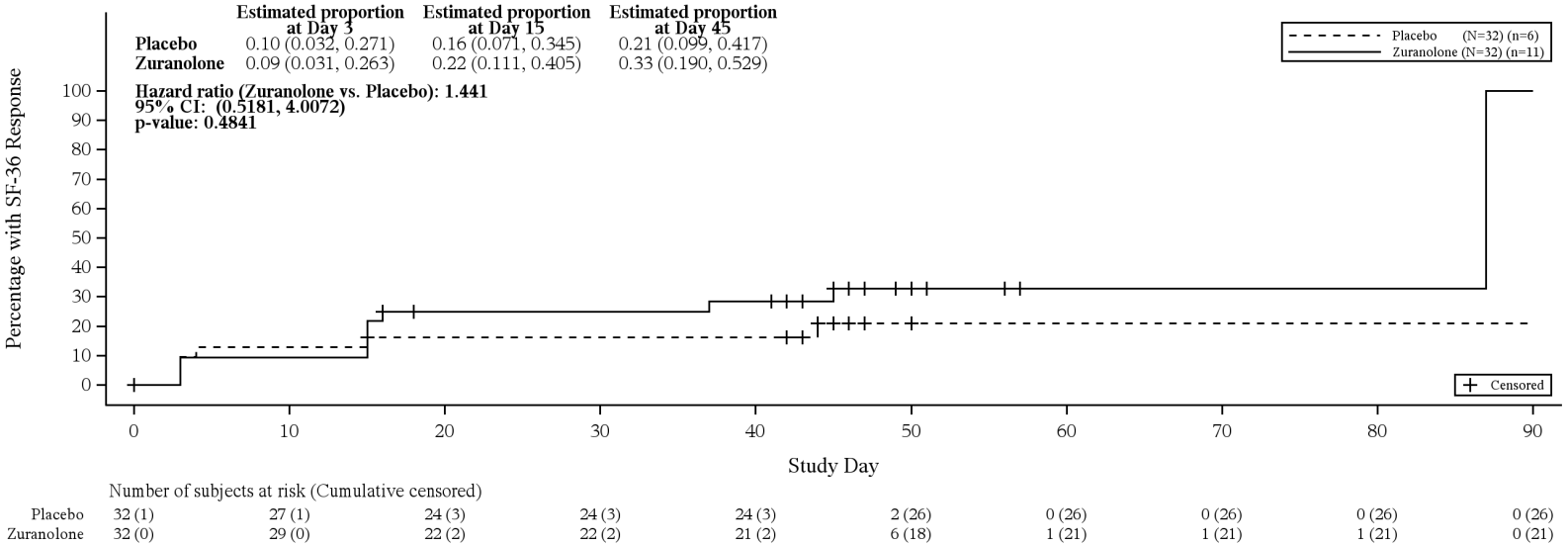
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis. NA: Not available due to non-convergence of the statistical model.

Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

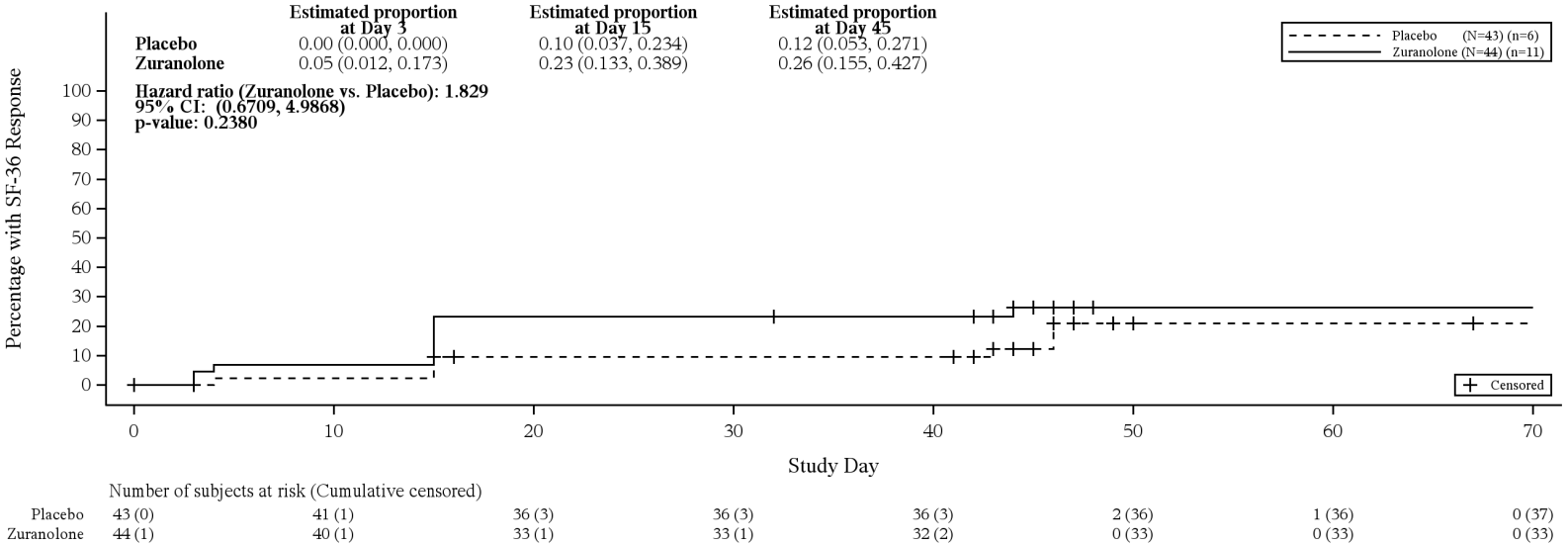
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis. NA: Not available due to non-convergence of the statistical model.

Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



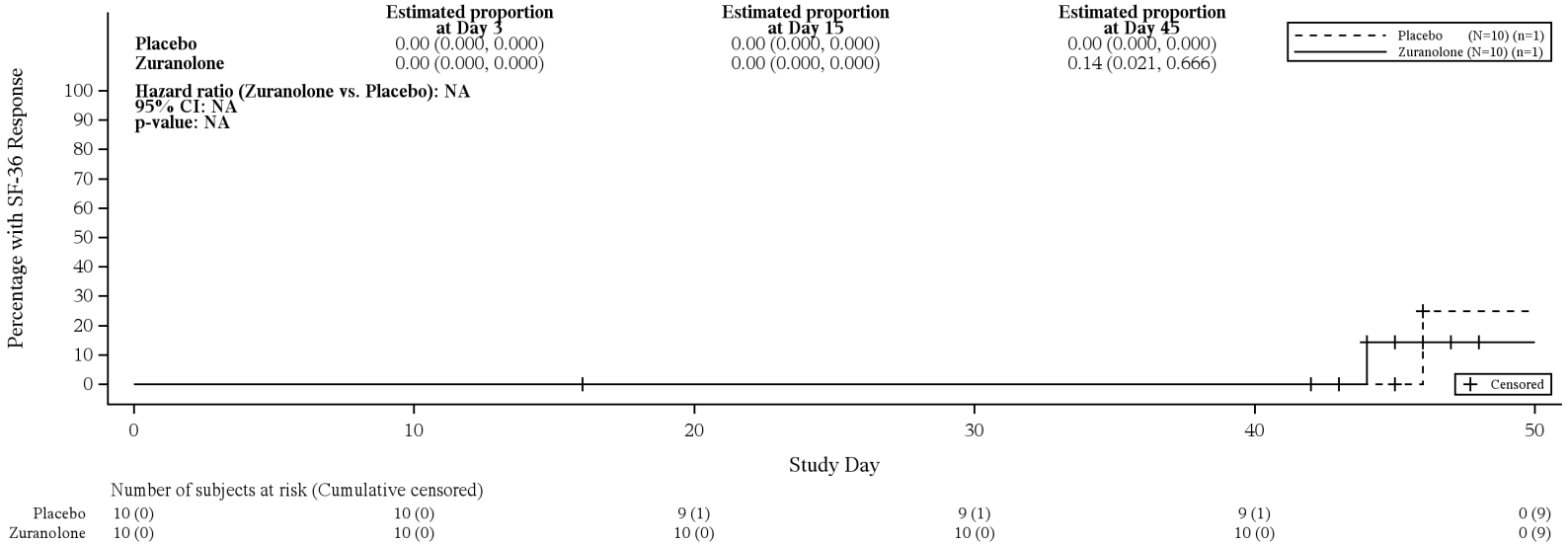
Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
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NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
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Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



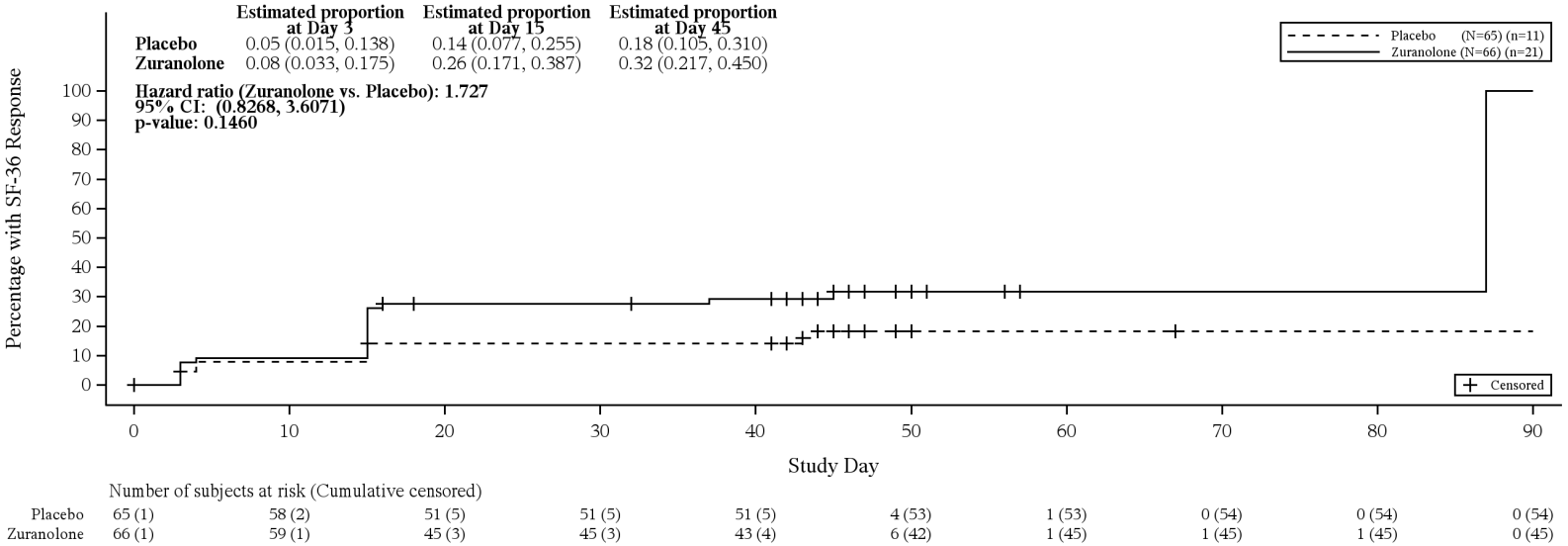
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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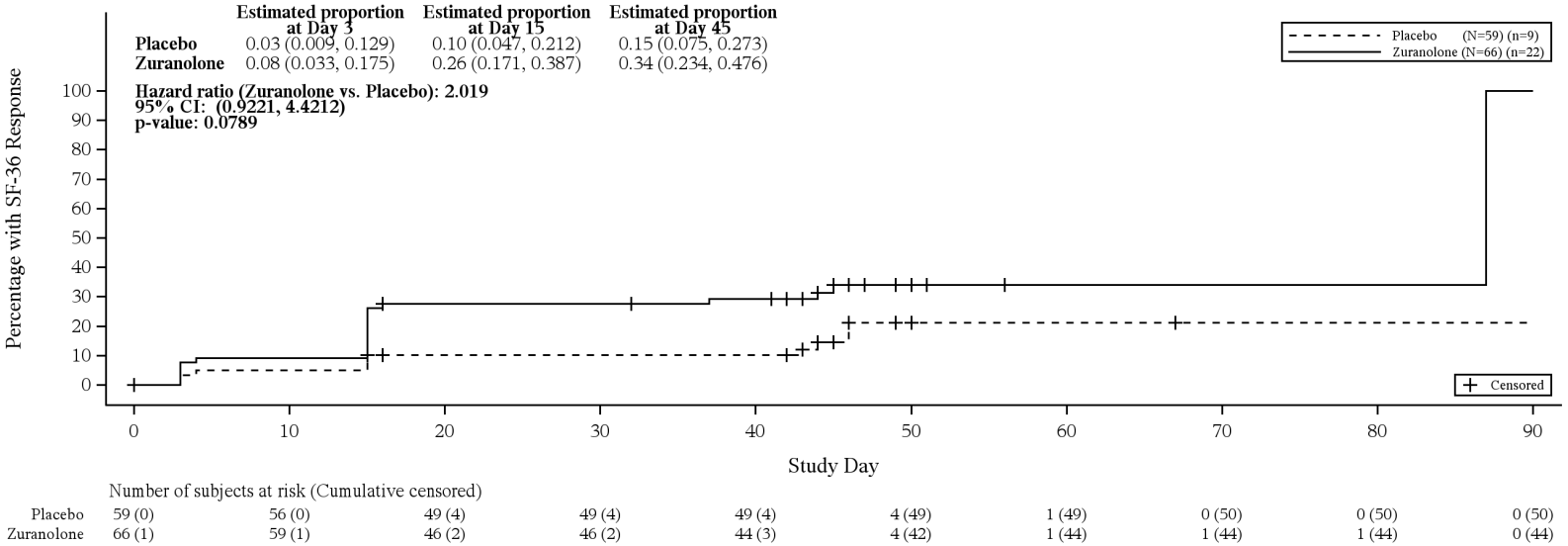
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Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



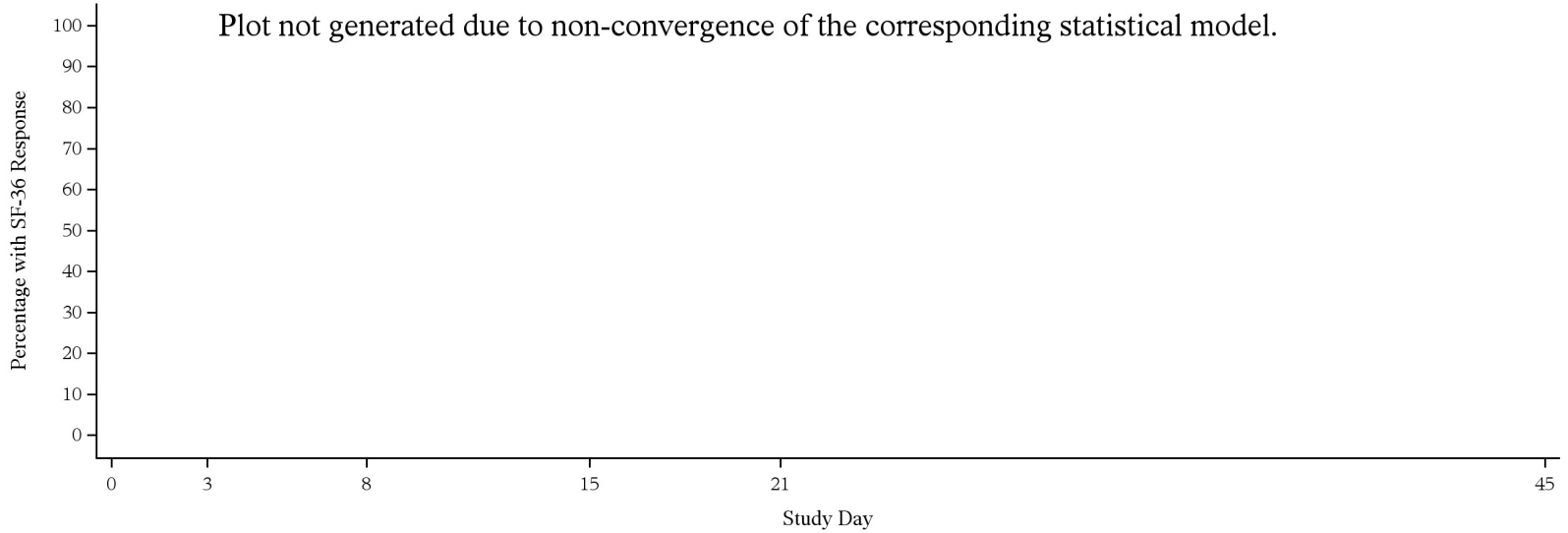
Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
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Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 Physical Component Summary score response is defined as 9.4 points (15% of total scale range) or greater increase in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis. NA: Not available due to non-convergence of the statistical model.

Source: biib125/v_a/amnog_kmplots/f-sf36-phys-resp15-tte-201-by.sas:f-sf36-phys-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

2.2.3 Verschlechterung

2.2.3.1 Responder-Analysen

2.2.3.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with worsening, n (%) [2]	10 (13.3)	4 (5.3)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.475
95% CI for the RR		(0.177, 1.275)
p-value for RR		0.1395
OR - Odds Ratio (Zuranolone vs. Placebo)		0.363
95% CI for the OR		(0.082, 1.602)
p-value for OR		0.1809
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score worsening (9.4 points (15% of total scale range) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-wors15-201-ovr.sas:t-sf36-phys-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	9 (12.0)	6 (7.9)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.791
95% CI for the RR		(0.353, 1.774)
p-value for RR		0.5696
OR - Odds Ratio (Zuranolone vs. Placebo)		0.760
95% CI for the OR		(0.228, 2.532)
p-value for OR		0.6552
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Component Summary score worsening (9.4 points (15% of total scale range) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-phys-wors15-201-ovr.sas:t-sf36-phys-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.2.3.1 .2 Subgruppen

2.2.3.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	10 (13.3)	4 (5.3)	
Number of subjects with response at Day 45, n (%)	9 (12.0)	6 (7.9)	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	4/25 (16.0)	0/17	
25 - 45, n / N (%)	6/50 (12.0)	4/59 (6.8)	
Day 45			
18 - 24, n / N (%)	4/25 (16.0)	0/17	
25 - 45, n / N (%)	5/50 (10.0)	6/59 (10.2)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 Physical Component Summary score worsening is defined as 9.4 points (15% of total scale range) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-wors15-201-int.sas:t-sf36-phys-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	3/22 (13.6)	2/30 (6.7)	
>=28, n / N (%)	7/53 (13.2)	2/46 (4.3)	
Day 45			
<28, n / N (%)	3/22 (13.6)	1/30 (3.3)	
>=28, n / N (%)	6/53 (11.3)	5/46 (10.9)	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	3/32 (9.4)	1/31 (3.2)	
White, n / N (%)	7/40 (17.5)	3/44 (6.8)	
Day 45			
Black or African American, n / N (%)	4/32 (12.5)	0/31	
White, n / N (%)	5/40 (12.5)	6/44 (13.6)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 Physical Component Summary score worsening is defined as 9.4 points (15% of total scale range) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-wors15-201-int.sas:t-sf36-phys-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	1/13 (7.7)	1/16 (6.3)	
No, n / N (%)	9/62 (14.5)	3/60 (5.0)	
Day 45			
Yes, n / N (%)	1/13 (7.7)	1/16 (6.3)	
No, n / N (%)	8/62 (12.9)	5/60 (8.3)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 Physical Component Summary score worsening is defined as 9.4 points (15% of total scale range) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-wors15-201-int.sas:t-sf36-phys-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	4/21 (19.0)	1/13 (7.7)	
25-29.9, n / N (%)	3/20 (15.0)	0/21	
>=30, n / N (%)	3/34 (8.8)	3/42 (7.1)	
Day 45			
<=24.9, n / N (%)	4/21 (19.0)	3/13 (23.1)	
25-29.9, n / N (%)	4/20 (20.0)	1/21 (4.8)	
>=30, n / N (%)	1/34 (2.9)	2/42 (4.8)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 Physical Component Summary score worsening is defined as 9.4 points (15% of total scale range) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-wors15-201-int.sas:t-sf36-phys-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 5 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	5/32 (15.6)	0/32	
Postpartum, n / N (%)	5/43 (11.6)	4/44 (9.1)	
Day 45			
3rd Trimester, n / N (%)	5/32 (15.6)	1/32 (3.1)	
Postpartum, n / N (%)	4/43 (9.3)	5/44 (11.4)	
Family History of PPD			NE
Day 15			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	10/65 (15.4)	4/66 (6.1)	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	9/65 (13.8)	6/66 (9.1)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 Physical Component Summary score worsening is defined as 9.4 points (15% of total scale range) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-wors15-201-int.sas:t-sf36-phys-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Component Summary Scores Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 6 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	8/59 (13.6)	4/66 (6.1)	
Recurrent Episode, n / N (%)	2/16 (12.5)	0/10	
Day 45			
1st Episode, n / N (%)	7/59 (11.9)	6/66 (9.1)	
Recurrent Episode, n / N (%)	2/16 (12.5)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	1/8 (12.5)	0/10	
>=20, n / N (%)	9/67 (13.4)	4/66 (6.1)	
Day 45			
<20, n / N (%)	1/8 (12.5)	1/10 (10.0)	
>=20, n / N (%)	8/67 (11.9)	5/66 (7.6)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 Physical Component Summary score worsening is defined as 9.4 points (15% of total scale range) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-wors15-201-int.sas:t-sf36-phys-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

2.2.3.1 .2 .2 Subgruppenanalysen

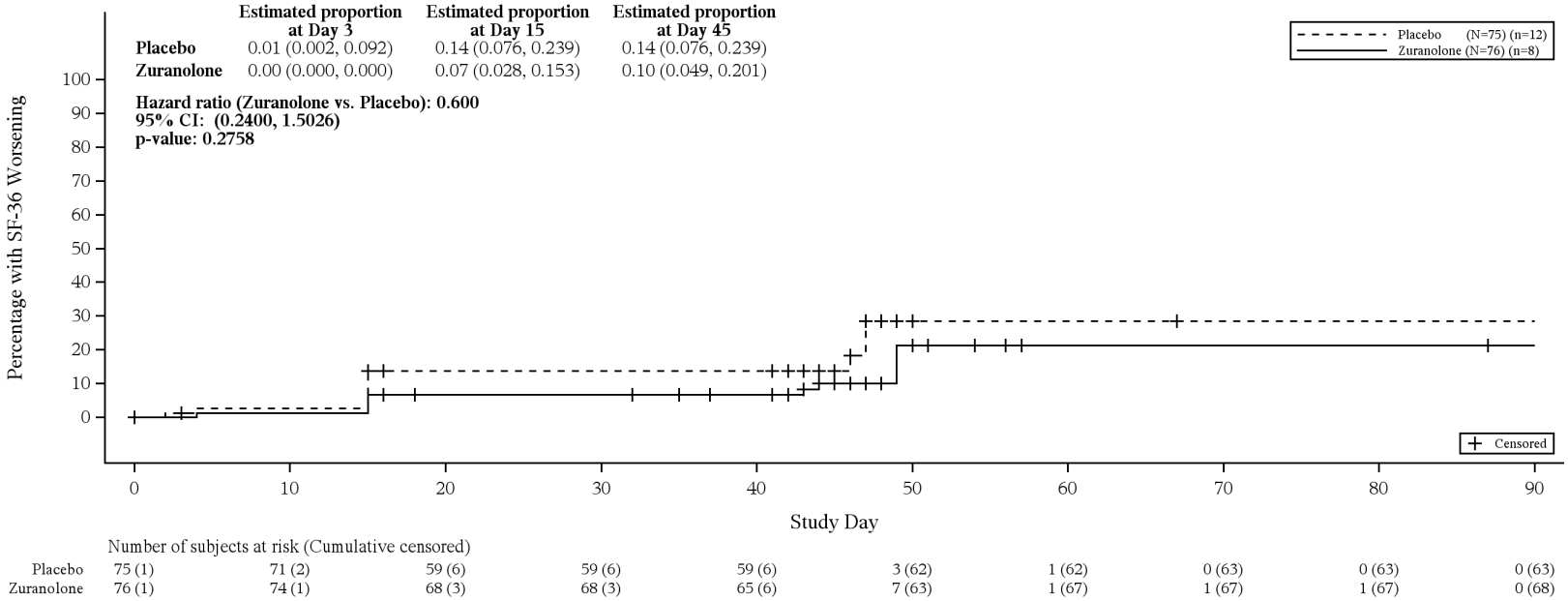
Nicht zutreffend.

2.2.3.2 TTE-Analysen

2.2.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Component Summary Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing SF-36 Physical Component Summary score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 Physical Component Summary score worsening is defined as 9.4 points (15% of total scale range) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-phys-wors15-tte-201-ovr.sas:f-sf36-phys-wors15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	12 (16.0)	8 (10.5)
Time to first Physical Component Summary worsening (days) [3]		
25th percentile - Q1 (95% CI)	47.0 (46.0, NE)	NE (49.0, NE)
50th percentile - median (95% CI)	NE (47.0, NE)	NE (49.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.600
95% CI for the HR		(0.2400 , 1.5026)
p-value for the HR		0.2758

NOTE 1: SF-36 Physical Component Summary score worsening is defined as 9.4 points (15% of total scale range) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing SF-36 Physical Component Summary score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Component Summary score worsening. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, and treatment.
Source: biib125/v_a/germany_amnog/t-sf36-phys-wors15-tte-201-ovr.sas:t-sf36-phys-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.2.3.2 .2 Subgruppen

2.2.3.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	12 (16.0)	8 (10.5)	
Age Group (years)			
18 - 24, n / N (%)	5/25 (20.0)	0/17	NA
25 - 45, n / N (%)	7/50 (14.0)	8/59 (13.6)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	3/22 (13.6)	2/30 (6.7)	NA
>=28, n / N (%)	9/53 (17.0)	6/46 (13.0)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	5/32 (15.6)	2/31 (6.5)	NA
White, n / N (%)	7/40 (17.5)	6/44 (13.6)	
Antidepressant Use at Baseline			
Yes, n / N (%)	1/13 (7.7)	1/16 (6.3)	0.3154
No, n / N (%)	11/62 (17.7)	7/60 (11.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Physical Component Summary score worsening is defined as 9.4 points (15% of total scale range) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-wors15-tte-201-int.sas:t-sf36-phys-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Component Summary Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	5/21 (23.8)	3/13 (23.1)	NA(a)
25-29.9, n / N (%)	4/20 (20.0)	1/21 (4.8)	NA(b)
>=30, n / N (%)	3/34 (8.8)	4/42 (9.5)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	6/32 (18.8)	1/32 (3.1)	NA
Postpartum, n / N (%)	6/43 (14.0)	7/44 (15.9)	
Family History of PPD			
Yes, n / N (%)	0/10	0/10	0.9996
No/Unknown, n / N (%)	12/65 (18.5)	8/66 (12.1)	
History of PPD			
1st Episode, n / N (%)	9/59 (15.3)	8/66 (12.1)	NA
Recurrent Episode, n / N (%)	3/16 (18.8)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	1/8 (12.5)	1/10 (10.0)	NA
>=20, n / N (%)	11/67 (16.4)	7/66 (10.6)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 Physical Component Summary score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 Physical Component Summary score worsening is defined as 9.4 points (15% of total scale range) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-phys-wors15-tte-201-int.sas:t-sf36-phys-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.2.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

2.2.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

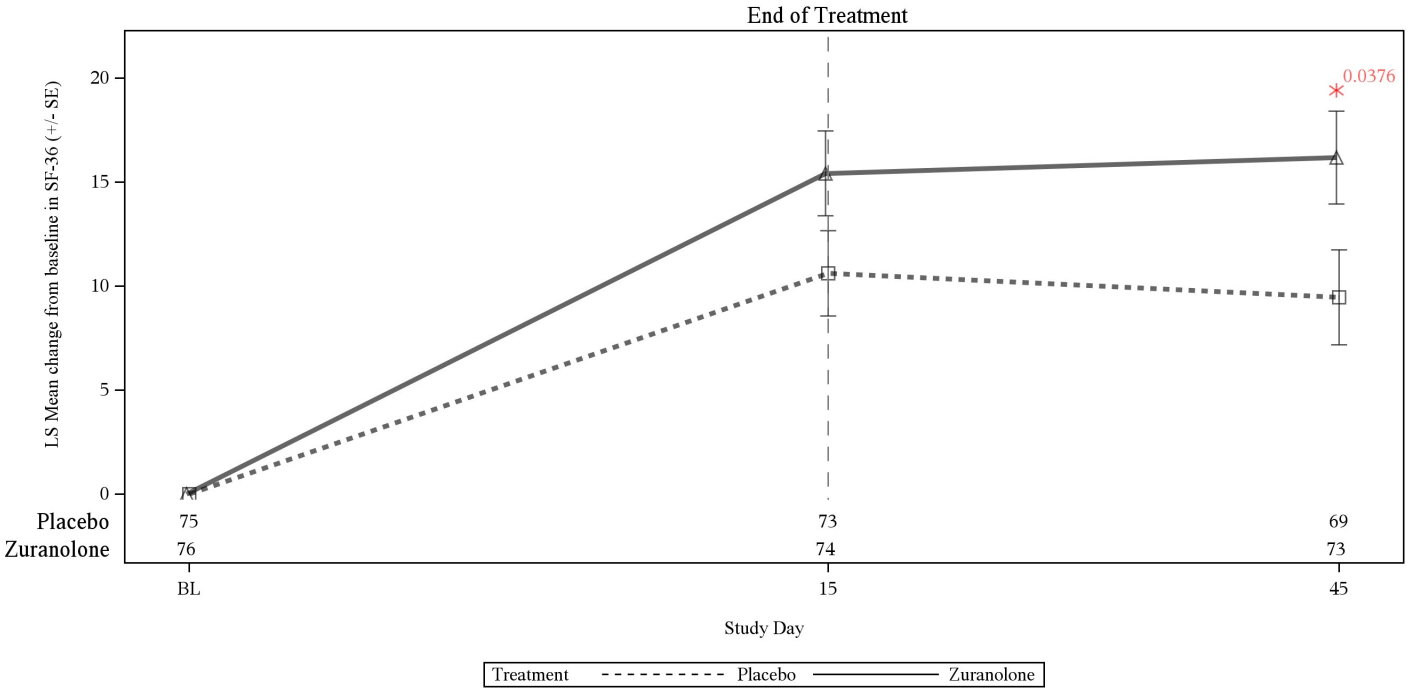
2.3 körperliche Funktionsfähigkeit

2.3.1 MMRM

2.3.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-ovr.sas:f-sf36-pf-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale: 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	10.61 (2.049)	15.42 (2.031)
95% CI for the LS Mean	6.56, 14.66	11.41, 19.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.82 (2.889)
95% CI for the LS Mean		-0.89, 10.53
p-value		0.0976
Hedges' g (Zuranolone vs. Placebo)		0.274
95% CI for Hedges' g		-0.0511, 0.5985
Day 45		
n	69	73
LS Mean (SE)	9.46 (2.283)	16.17 (2.231)
95% CI for the LS Mean	4.95, 13.97	11.76, 20.58
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.71 (3.196)
95% CI for the LS Mean		0.39, 13.03
p-value		0.0376
Hedges' g (Zuranolone vs. Placebo)		0.351
95% CI for Hedges' g		0.0190, 0.6822

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-ovr.sas:t-sf36-pf-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.3.1.2 Subgruppen

2.3.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.5853
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.0691
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.3735
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.8850
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-int.sas:t-sf36-pf-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.6321(a)
25-29.9	20	21	0.3959(b)
>=30	34	42	0.7270(c)
Onset of PPD			
3rd Trimester	32	32	0.3396
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.8918
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.8005
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-int.sas:t-sf36-pf-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

2.3.1.2 .2 Subgruppenanalysen

2.3.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	11.72 (3.943)	19.12 (4.799)
95% CI for the LS Mean	3.74, 19.70	9.40, 28.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.40 (6.297)
95% CI for the LS Mean		-5.34, 20.13
p-value		0.2472
Hedges' g (Zuranolone vs. Placebo)		0.362
95% CI for Hedges' g		-0.2587, 0.9833
Day 45		
n	25	16
LS Mean (SE)	6.12 (2.920)	22.25 (3.698)
95% CI for the LS Mean	0.20, 12.04	14.76, 29.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		16.13 (4.841)
95% CI for the LS Mean		6.33, 25.93
p-value		0.0019
Hedges' g (Zuranolone vs. Placebo)		1.046
95% CI for Hedges' g		0.3788, 1.7130

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	9.31 (2.478)	14.86 (2.264)
95% CI for the LS Mean	4.39, 14.23	10.37, 19.35
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.55 (3.358)
95% CI for the LS Mean		-1.11, 12.22
p-value		0.1012
Hedges' g (Zuranolone vs. Placebo)		0.322
95% CI for Hedges' g		-0.0648, 0.7081
Day 45		
n	44	57
LS Mean (SE)	10.57 (3.027)	15.02 (2.708)
95% CI for the LS Mean	4.57, 16.57	9.65, 20.40
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.45 (4.064)
95% CI for the LS Mean		-3.61, 12.51
p-value		0.2757
Hedges' g (Zuranolone vs. Placebo)		0.218
95% CI for Hedges' g		-0.1762, 0.6127

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.3.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	11.50 (3.512)	9.86 (3.089)
95% CI for the LS Mean	4.43, 18.57	3.64, 16.08
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.64 (4.707)
95% CI for the LS Mean		-11.12, 7.83
p-value		0.7290
Hedges' g (Zuranolone vs. Placebo)		-0.098
95% CI for Hedges' g		-0.6565, 0.4610
Day 45		
n	22	28
LS Mean (SE)	9.68 (3.362)	12.00 (2.961)
95% CI for the LS Mean	2.92, 16.44	6.05, 17.96
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.32 (4.516)
95% CI for the LS Mean		-6.76, 11.40
p-value		0.6093
Hedges' g (Zuranolone vs. Placebo)		0.144
95% CI for Hedges' g		-0.4149, 0.7034

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	10.06 (2.491)	19.04 (2.625)
95% CI for the LS Mean	5.11, 15.01	13.82, 24.25
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.97 (3.621)
95% CI for the LS Mean		1.78, 16.17
p-value		0.0150
Hedges' g (Zuranolone vs. Placebo)		0.500
95% CI for Hedges' g		0.0952, 0.9046
Day 45		
n	47	45
LS Mean (SE)	9.15 (2.974)	19.00 (3.074)
95% CI for the LS Mean	3.24, 15.06	12.89, 25.11
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.85 (4.281)
95% CI for the LS Mean		1.35, 18.35
p-value		0.0237
Hedges' g (Zuranolone vs. Placebo)		0.476
95% CI for Hedges' g		0.0614, 0.8905

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.3.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	12.48 (3.916)	17.39 (3.916)
95% CI for the LS Mean	4.65, 20.32	9.55, 25.23
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.91 (5.543)
95% CI for the LS Mean		-6.19, 16.00
p-value		0.3796
Hedges' g (Zuranolone vs. Placebo)		0.222
95% CI for Hedges' g		-0.2773, 0.7214
Day 45		
n	30	30
LS Mean (SE)	8.69 (4.029)	21.47 (4.029)
95% CI for the LS Mean	0.62, 16.75	13.40, 29.53
Difference (Zuranolone - Placebo)		
LS Mean (SE)		12.78 (5.703)
95% CI for the LS Mean		1.36, 24.20
p-value		0.0289
Hedges' g (Zuranolone vs. Placebo)		0.571
95% CI for Hedges' g		0.0548, 1.0874

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Race Group: 217-PPD-201B - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	8.89 (2.165)	13.63 (2.078)
95% CI for the LS Mean	4.58, 13.21	9.49, 17.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.73 (3.025)
95% CI for the LS Mean		-1.29, 10.75
p-value		0.1220
Hedges' g (Zuranolone vs. Placebo)		0.344
95% CI for Hedges' g		-0.0946, 0.7836
Day 45		
n	36	42
LS Mean (SE)	9.44 (2.775)	11.74 (2.605)
95% CI for the LS Mean	3.91, 14.96	6.55, 16.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.30 (3.825)
95% CI for the LS Mean		-5.31, 9.92
p-value		0.5491
Hedges' g (Zuranolone vs. Placebo)		0.135
95% CI for Hedges' g		-0.3103, 0.5810

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.3.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	6.24 (3.291)	15.47 (3.063)
95% CI for the LS Mean	-0.55, 13.03	9.15, 21.79
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.23 (4.495)
95% CI for the LS Mean		-0.04, 18.51
p-value		0.0509
Hedges' g (Zuranolone vs. Placebo)		0.756
95% CI for Hedges' g		-0.0128, 1.5245
Day 45		
n	11	15
LS Mean (SE)	13.14 (3.605)	16.81 (3.211)
95% CI for the LS Mean	5.70, 20.58	10.15, 23.46
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.67 (4.828)
95% CI for the LS Mean		-6.31, 13.65
p-value		0.4547
Hedges' g (Zuranolone vs. Placebo)		0.292
95% CI for Hedges' g		-0.4898, 1.0743

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	11.57 (2.399)	15.39 (2.413)
95% CI for the LS Mean	6.81, 16.32	10.61, 20.17
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.83 (3.407)
95% CI for the LS Mean		-2.92, 10.58
p-value		0.2636
Hedges' g (Zuranolone vs. Placebo)		0.205
95% CI for Hedges' g		-0.1557, 0.5649
Day 45		
n	58	58
LS Mean (SE)	8.88 (2.667)	15.98 (2.667)
95% CI for the LS Mean	3.60, 14.16	10.70, 21.26
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.10 (3.776)
95% CI for the LS Mean		-0.38, 14.58
p-value		0.0626
Hedges' g (Zuranolone vs. Placebo)		0.347
95% CI for Hedges' g		-0.0198, 0.7136

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.3.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	9.53 (3.297)	14.26 (4.099)
95% CI for the LS Mean	2.77, 16.29	5.86, 22.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.73 (5.278)
95% CI for the LS Mean		-6.08, 15.55
p-value		0.3776
Hedges' g (Zuranolone vs. Placebo)		0.312
95% CI for Hedges' g		-0.3906, 1.0140
Day 45		
n	18	12
LS Mean (SE)	2.61 (3.675)	17.34 (4.502)
95% CI for the LS Mean	-4.96, 10.17	8.07, 26.60
Difference (Zuranolone - Placebo)		
LS Mean (SE)		14.73 (5.830)
95% CI for the LS Mean		2.74, 26.72
p-value		0.0180
Hedges' g (Zuranolone vs. Placebo)		0.916
95% CI for Hedges' g		0.1500, 1.6827

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	13.57 (4.409)	20.08 (4.375)
95% CI for the LS Mean	4.62, 22.51	11.21, 28.95
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.52 (6.245)
95% CI for the LS Mean		-6.15, 19.18
p-value		0.3038
Hedges' g (Zuranolone vs. Placebo)		0.323
95% CI for Hedges' g		-0.3005, 0.9472
Day 45		
n	20	20
LS Mean (SE)	13.99 (5.320)	17.19 (5.270)
95% CI for the LS Mean	3.18, 24.79	6.50, 27.89
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.21 (7.513)
95% CI for the LS Mean		-12.04, 18.46
p-value		0.6721
Hedges' g (Zuranolone vs. Placebo)		0.132
95% CI for Hedges' g		-0.4882, 0.7528

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	9.44 (3.064)	13.40 (2.747)
95% CI for the LS Mean	3.33, 15.56	7.92, 18.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.96 (4.123)
95% CI for the LS Mean		-4.26, 12.18
p-value		0.3404
Hedges' g (Zuranolone vs. Placebo)		0.222
95% CI for Hedges' g		-0.2376, 0.6819
Day 45		
n	31	41
LS Mean (SE)	10.43 (3.030)	15.23 (2.671)
95% CI for the LS Mean	4.39, 16.47	9.90, 20.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.80 (4.047)
95% CI for the LS Mean		-3.27, 12.88
p-value		0.2392
Hedges' g (Zuranolone vs. Placebo)		0.280
95% CI for Hedges' g		-0.1892, 0.7482

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.3.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	9.45 (3.373)	14.89 (3.318)
95% CI for the LS Mean	2.71, 16.20	8.26, 21.53
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.44 (4.749)
95% CI for the LS Mean		-4.06, 14.94
p-value		0.2566
Hedges' g (Zuranolone vs. Placebo)		0.285
95% CI for Hedges' g		-0.2113, 0.7815
Day 45		
n	29	30
LS Mean (SE)	5.95 (3.814)	18.40 (3.751)
95% CI for the LS Mean	-1.68, 13.59	10.89, 25.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		12.44 (5.362)
95% CI for the LS Mean		1.71, 23.18
p-value		0.0239
Hedges' g (Zuranolone vs. Placebo)		0.596
95% CI for Hedges' g		0.0746, 1.1179

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	11.30 (2.595)	15.95 (2.584)
95% CI for the LS Mean	6.13, 16.46	10.81, 21.10
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.66 (3.668)
95% CI for the LS Mean		-2.65, 11.96
p-value		0.2081
Hedges' g (Zuranolone vs. Placebo)		0.274
95% CI for Hedges' g		-0.1553, 0.7041
Day 45		
n	40	43
LS Mean (SE)	11.88 (2.812)	14.77 (2.738)
95% CI for the LS Mean	6.29, 17.47	9.32, 20.22
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.89 (3.931)
95% CI for the LS Mean		-4.93, 10.71
p-value		0.4645
Hedges' g (Zuranolone vs. Placebo)		0.160
95% CI for Hedges' g		-0.2713, 0.5912

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.3.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	4.40 (3.659)	11.09 (3.702)
95% CI for the LS Mean	-3.35, 12.16	3.25, 18.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.69 (5.347)
95% CI for the LS Mean		-4.64, 18.01
p-value		0.2290
Hedges' g (Zuranolone vs. Placebo)		0.536
95% CI for Hedges' g		-0.3565, 1.4277
Day 45		
n	9	10
LS Mean (SE)	10.44 (4.952)	12.59 (4.917)
95% CI for the LS Mean	0.04, 20.85	2.22, 22.95
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.15 (7.074)
95% CI for the LS Mean		-12.71, 17.00
p-value		0.7647
Hedges' g (Zuranolone vs. Placebo)		0.133
95% CI for Hedges' g		-0.7682, 1.0349

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	11.65 (2.288)	16.00 (2.264)
95% CI for the LS Mean	7.12, 16.18	11.51, 20.48
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.34 (3.222)
95% CI for the LS Mean		-2.04, 10.72
p-value		0.1803
Hedges' g (Zuranolone vs. Placebo)		0.238
95% CI for Hedges' g		-0.1113, 0.5868
Day 45		
n	60	63
LS Mean (SE)	9.42 (2.524)	16.63 (2.471)
95% CI for the LS Mean	4.42, 14.41	11.74, 21.52
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.21 (3.535)
95% CI for the LS Mean		0.22, 14.21
p-value		0.0434
Hedges' g (Zuranolone vs. Placebo)		0.366
95% CI for Hedges' g		0.0094, 0.7224

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.3.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	11.84 (2.391)	16.51 (2.289)
95% CI for the LS Mean	7.11, 16.58	11.98, 21.05
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.67 (3.322)
95% CI for the LS Mean		-1.91, 11.25
p-value		0.1625
Hedges' g (Zuranolone vs. Placebo)		0.252
95% CI for Hedges' g		-0.1030, 0.6072
Day 45		
n	55	64
LS Mean (SE)	11.37 (2.519)	17.13 (2.356)
95% CI for the LS Mean	6.38, 16.35	12.47, 21.80
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.77 (3.459)
95% CI for the LS Mean		-1.08, 12.62
p-value		0.0981
Hedges' g (Zuranolone vs. Placebo)		0.305
95% CI for Hedges' g		-0.0579, 0.6670

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-pf-mmrm-201-by.sas:t-sf36-pf-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	4.73 (3.897)	9.11 (4.737)
95% CI for the LS Mean	-3.39, 12.85	-0.76, 18.99
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.38 (6.569)
95% CI for the LS Mean		-9.30, 18.07
p-value		0.5120
Hedges' g (Zuranolone vs. Placebo)		0.267
95% CI for Hedges' g		-0.5482, 1.0818
Day 45		
n	14	9
LS Mean (SE)	1.16 (5.797)	10.68 (7.086)
95% CI for the LS Mean	-10.84, 13.16	-3.93, 25.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.52 (9.446)
95% CI for the LS Mean		-9.93, 28.97
p-value		0.3230
Hedges' g (Zuranolone vs. Placebo)		0.415
95% CI for Hedges' g		-0.4308, 1.2611

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

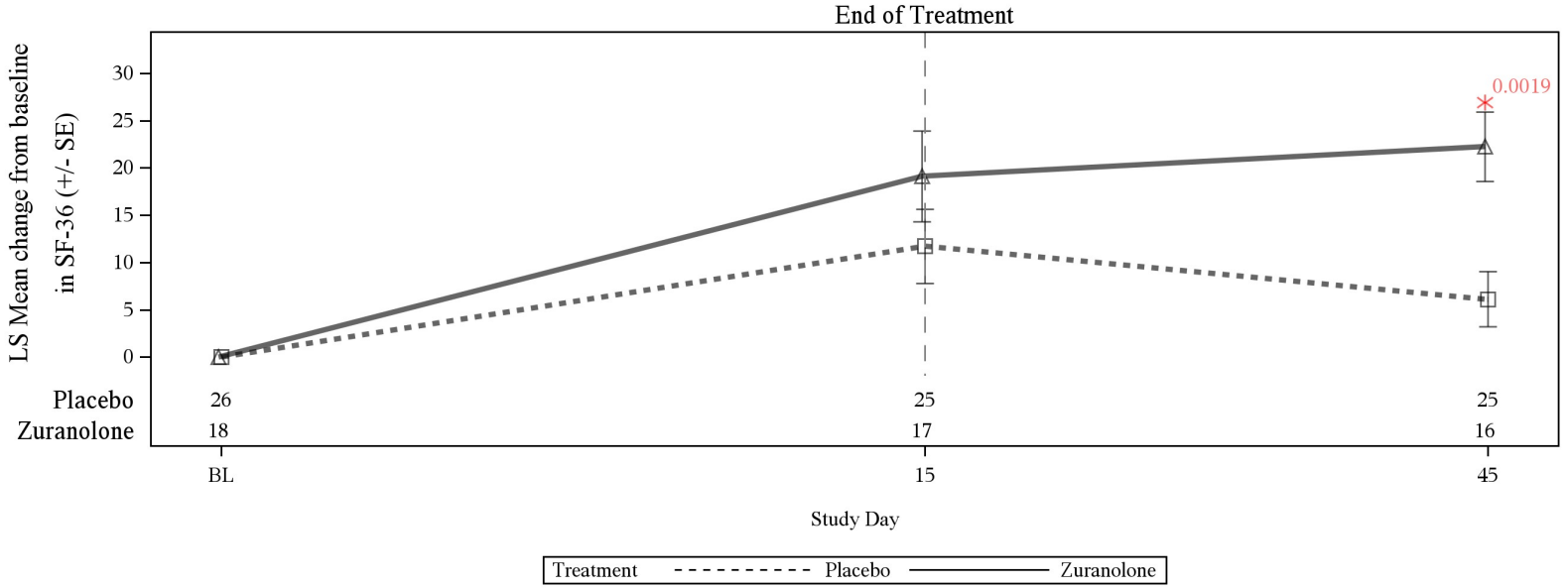
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2.3.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

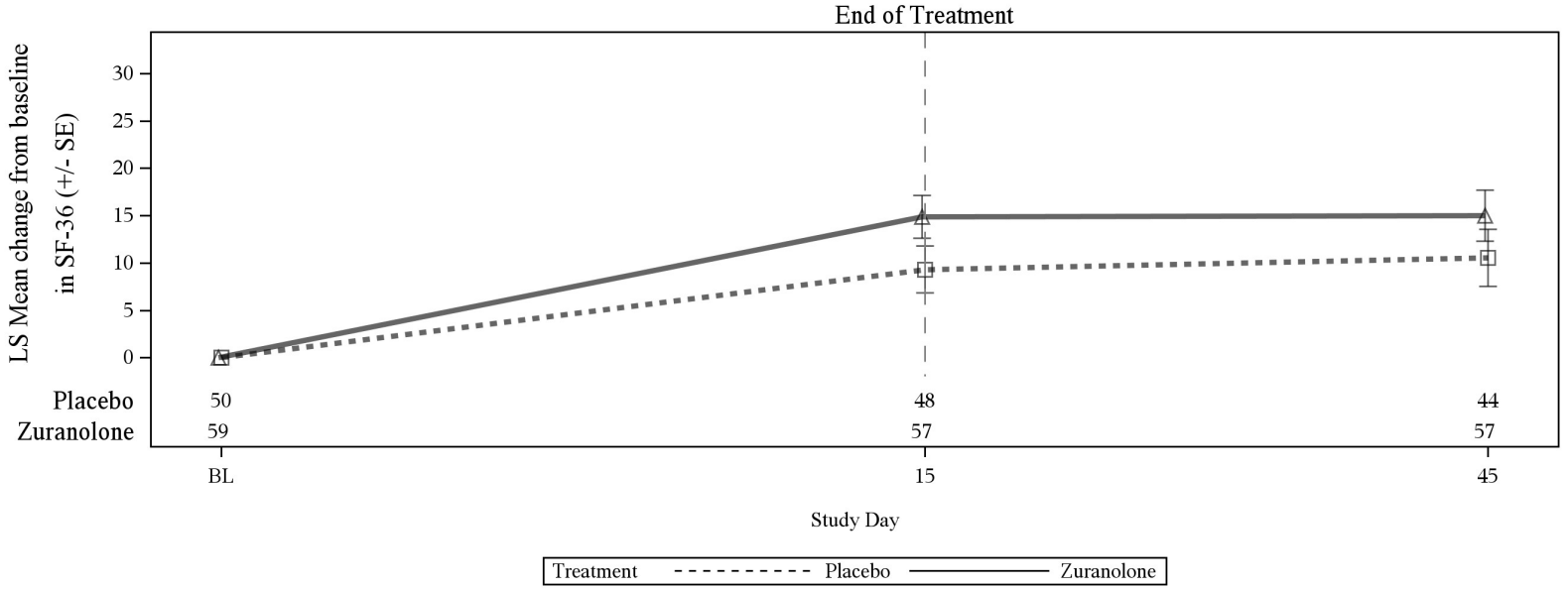
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Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

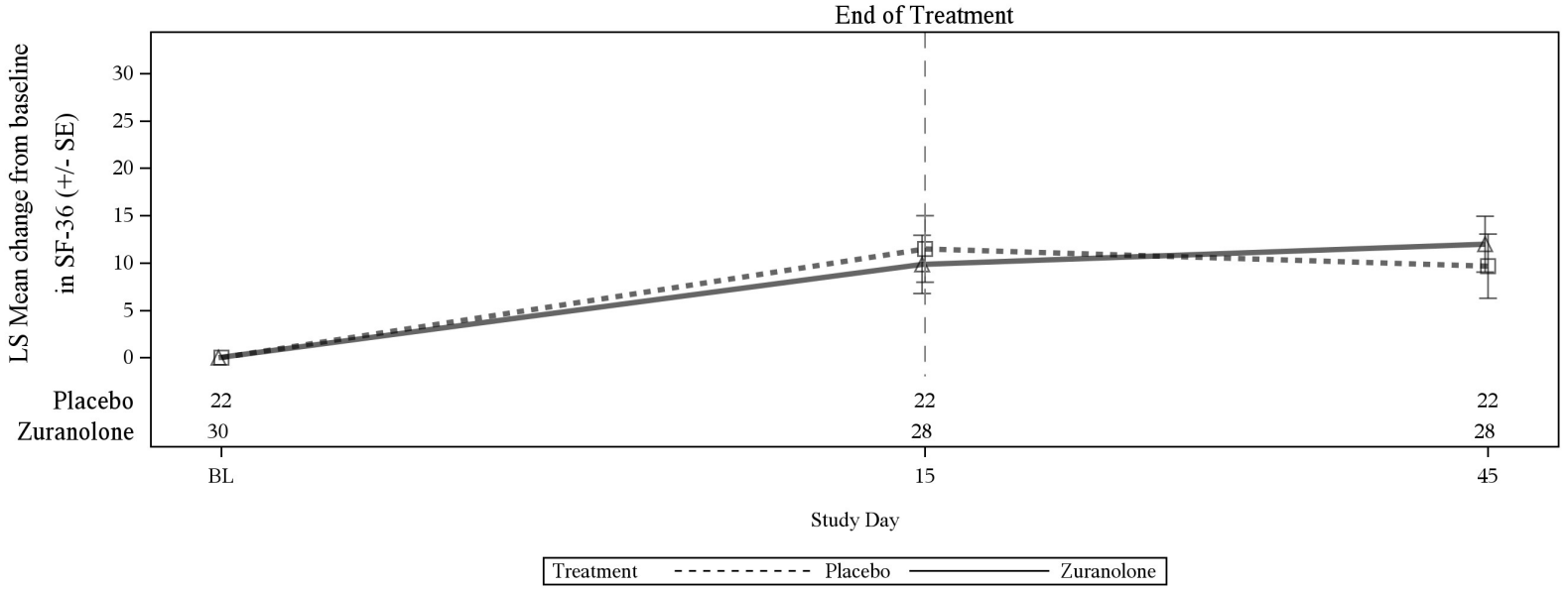
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

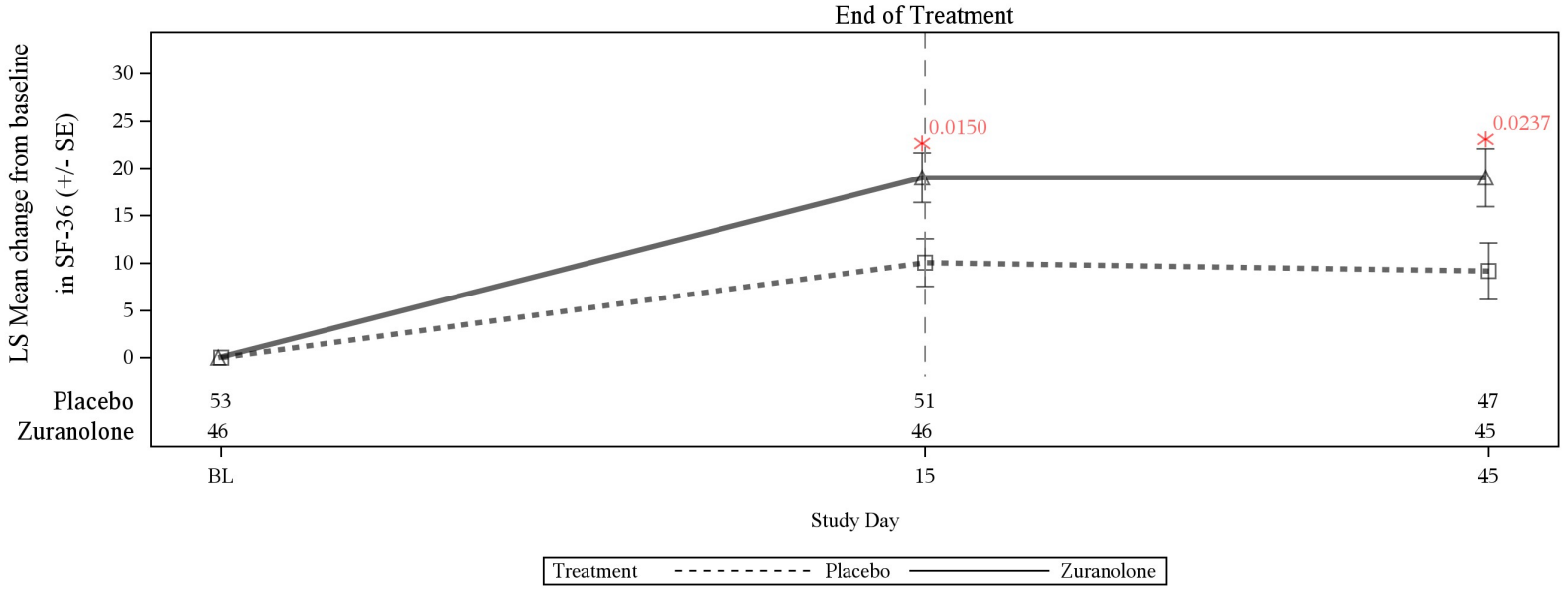
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

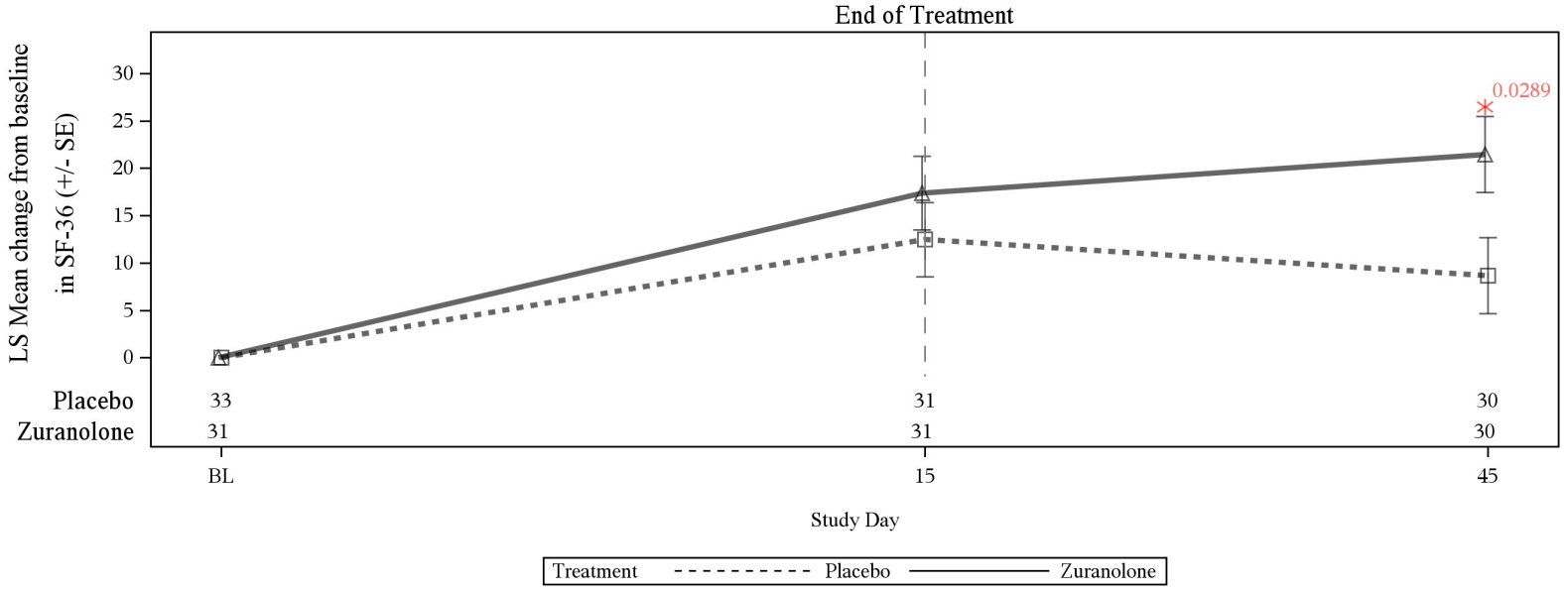
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Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

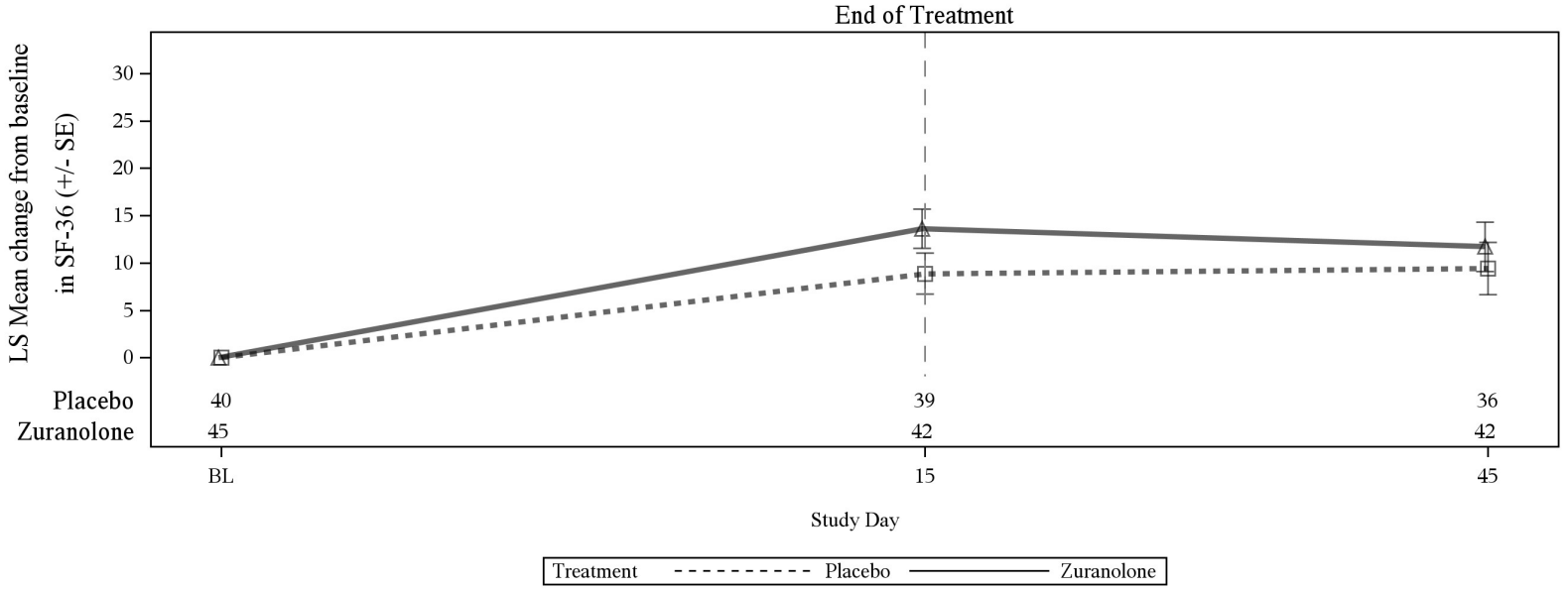
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Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

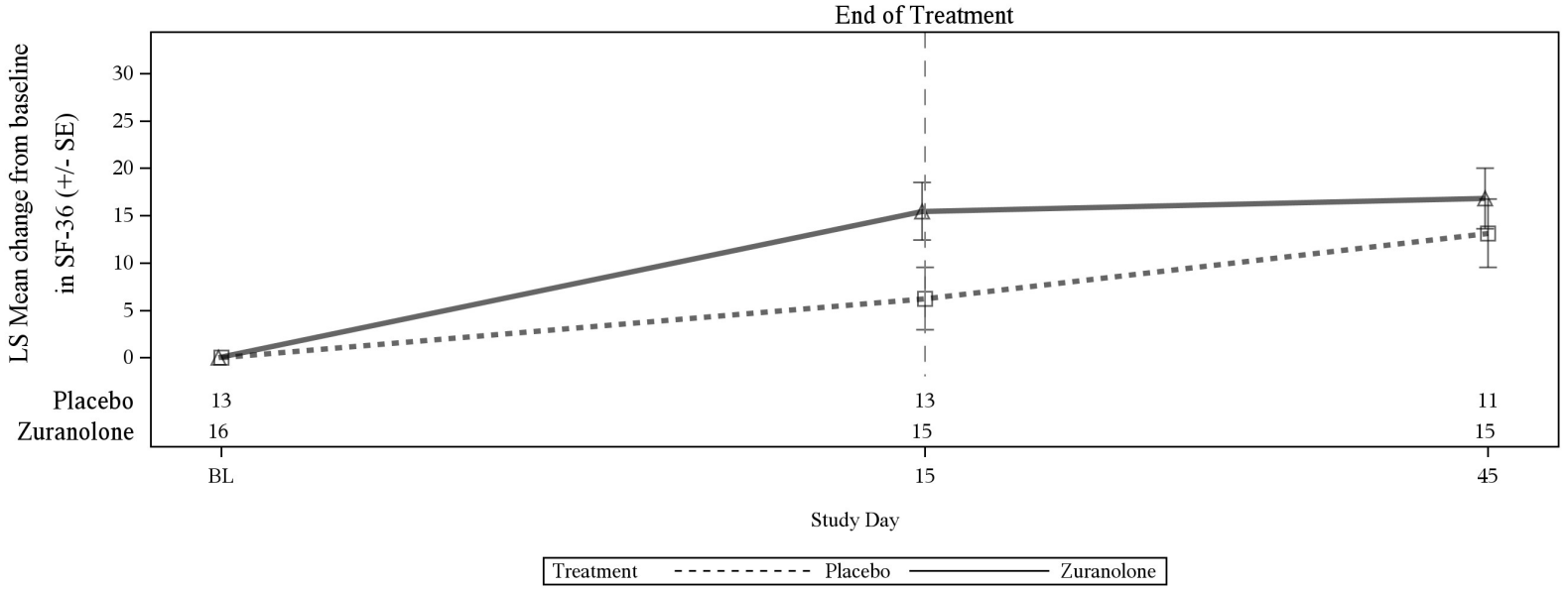
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 7 of 17

Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

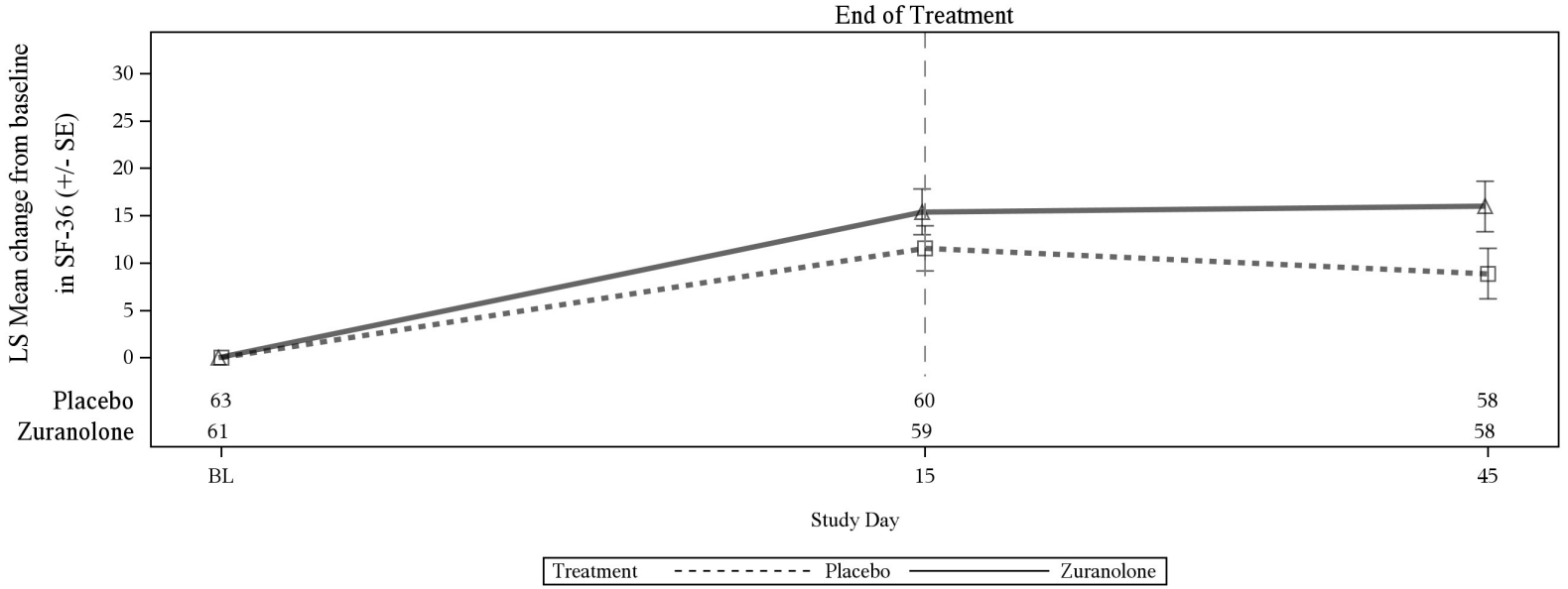
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Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

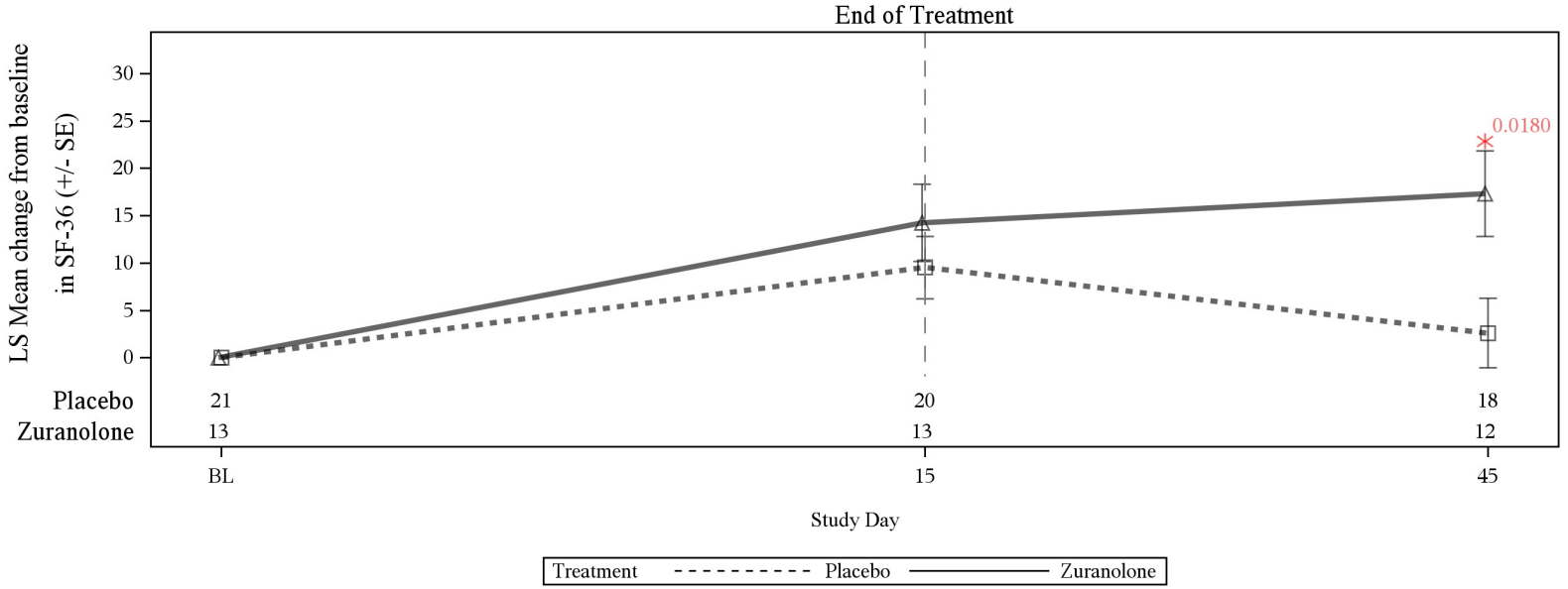
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Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

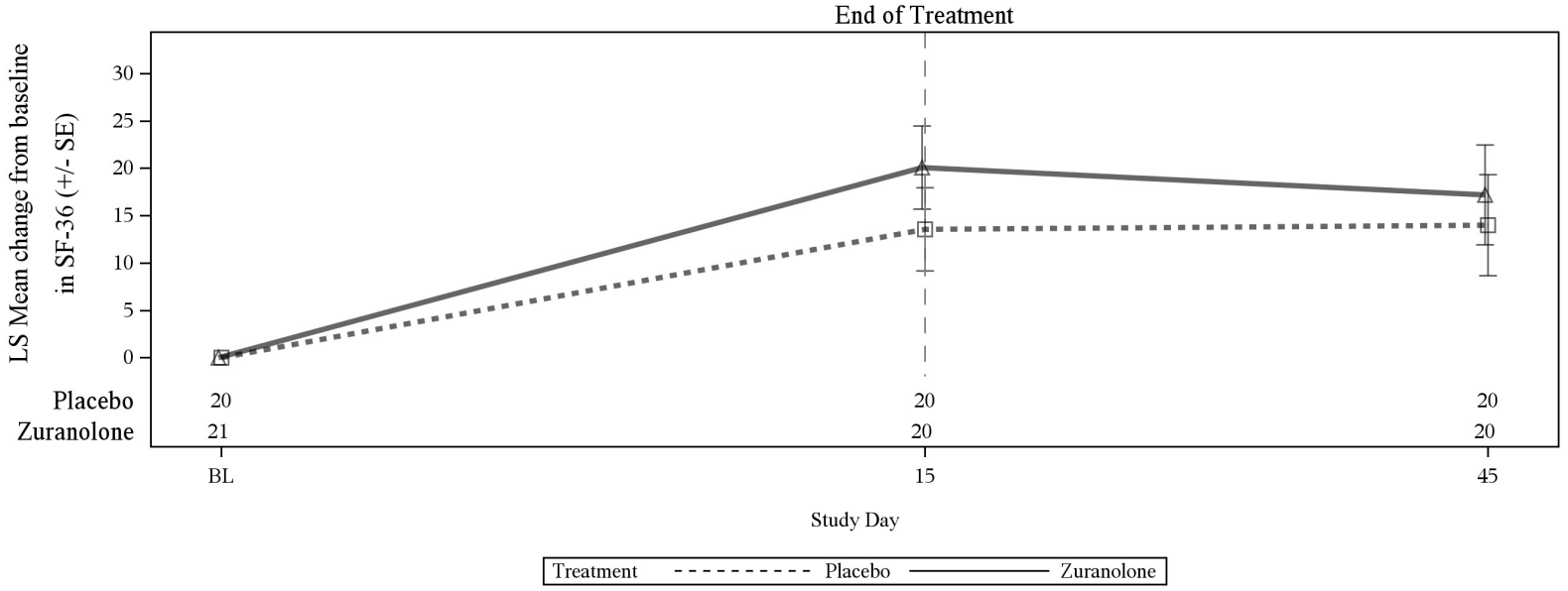
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

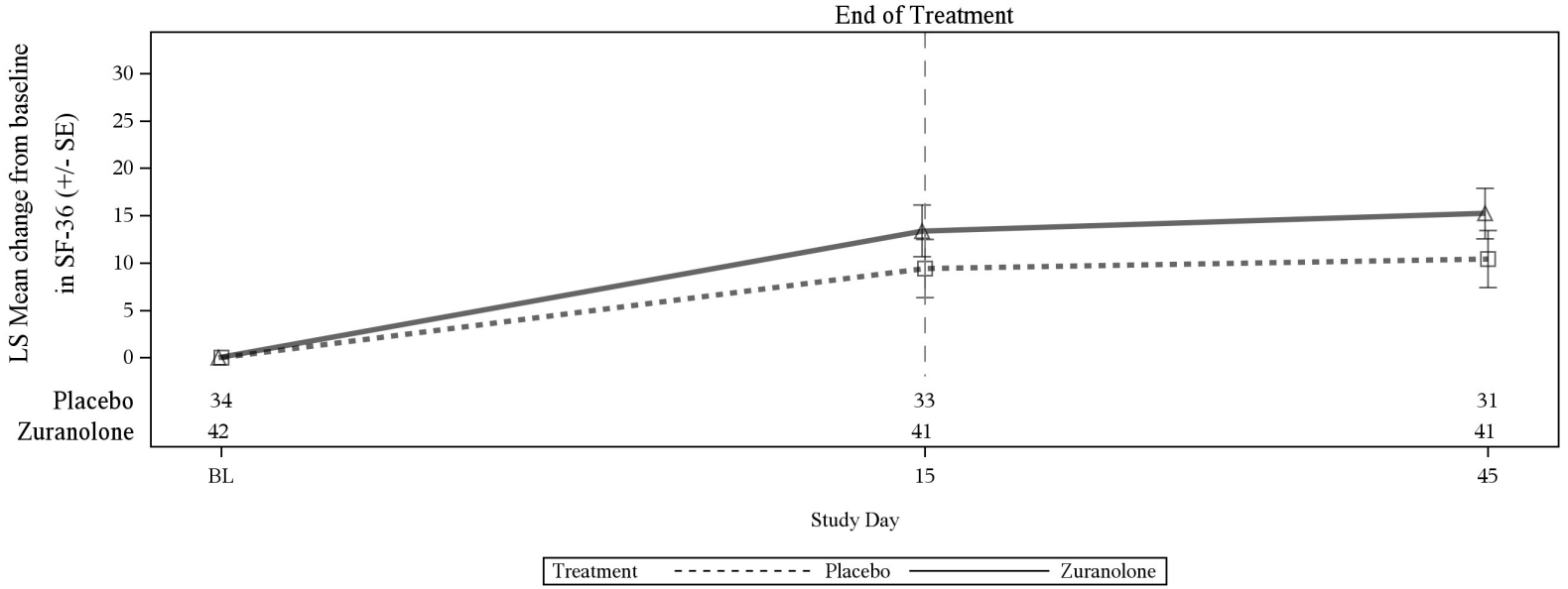
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

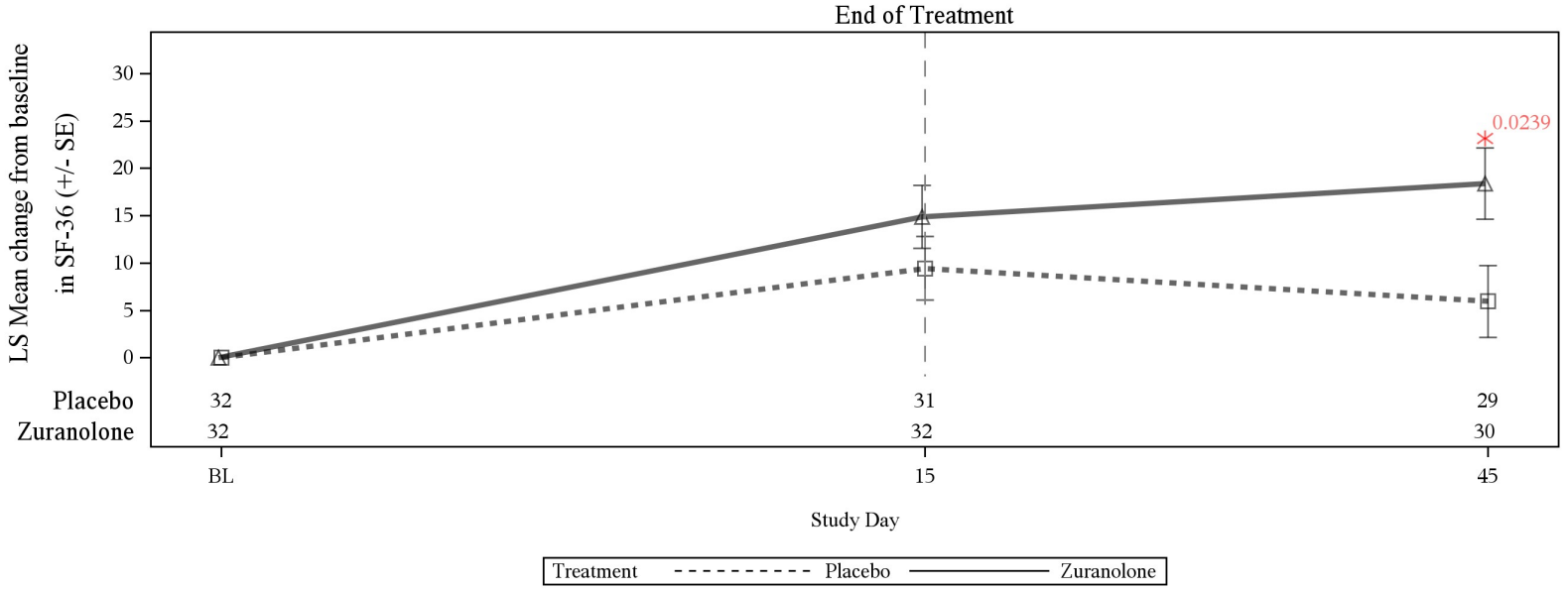
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

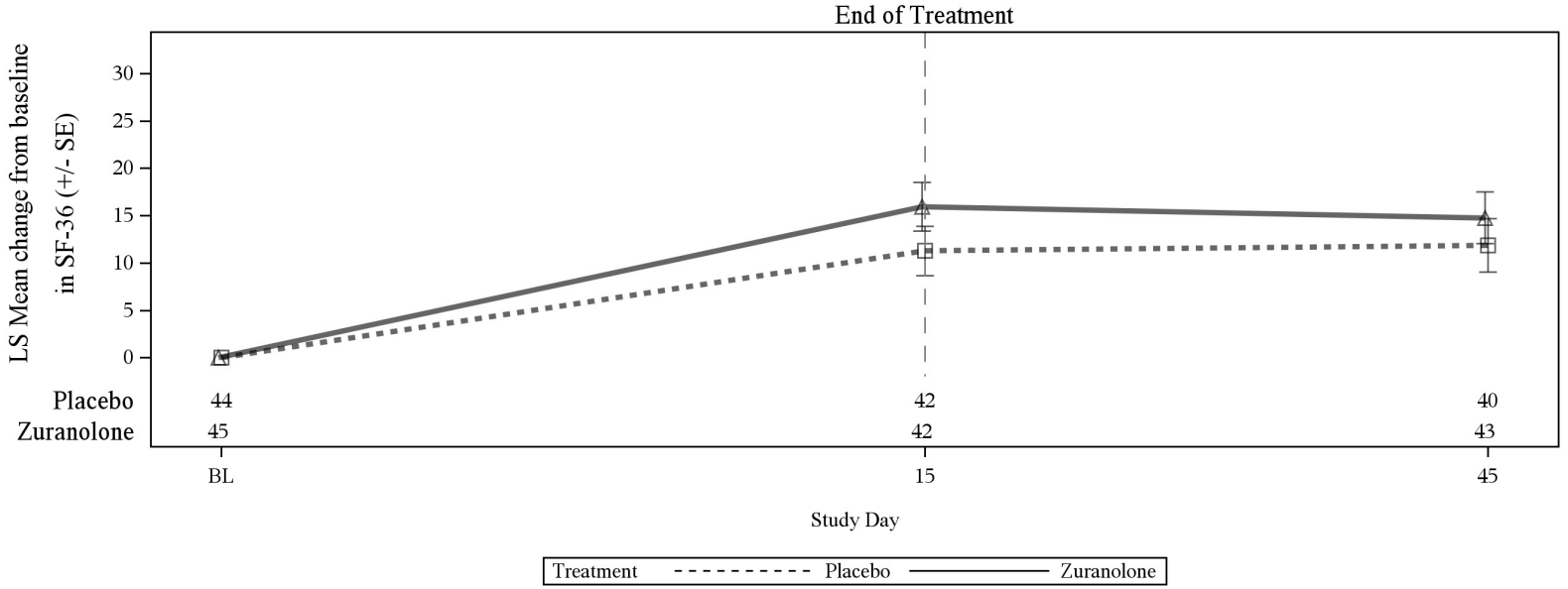
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

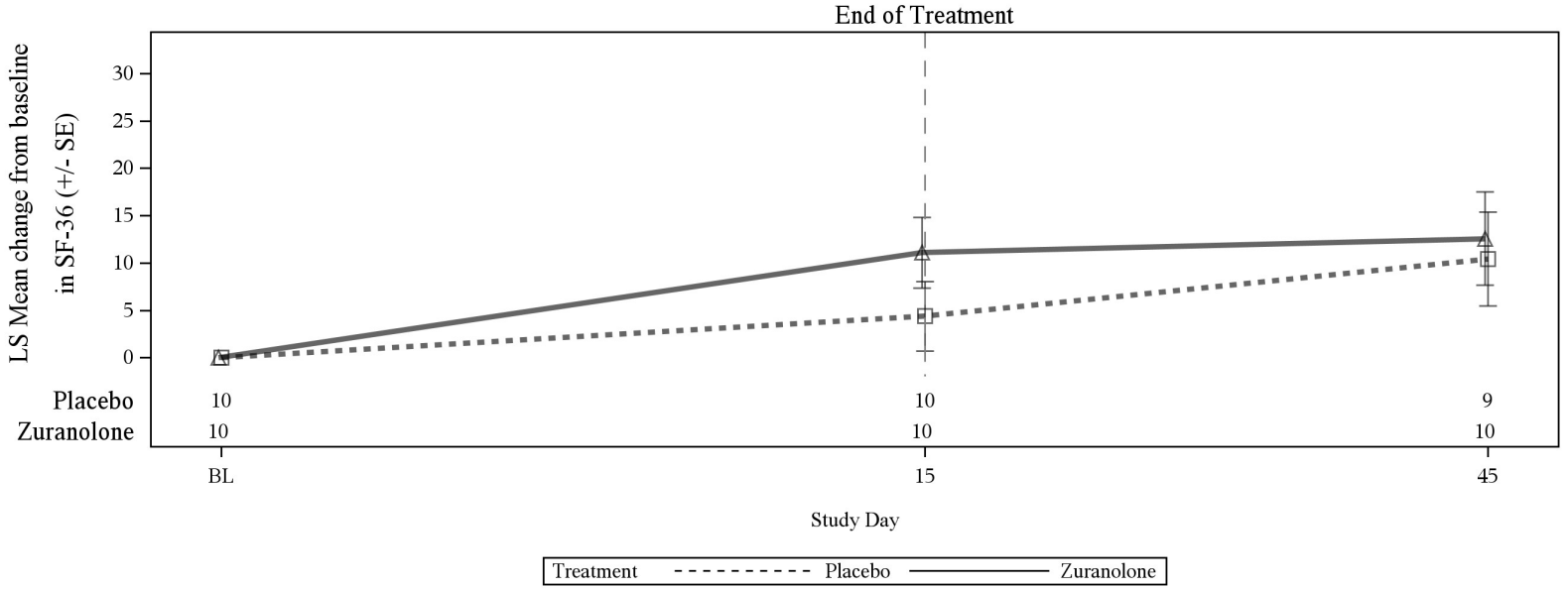
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

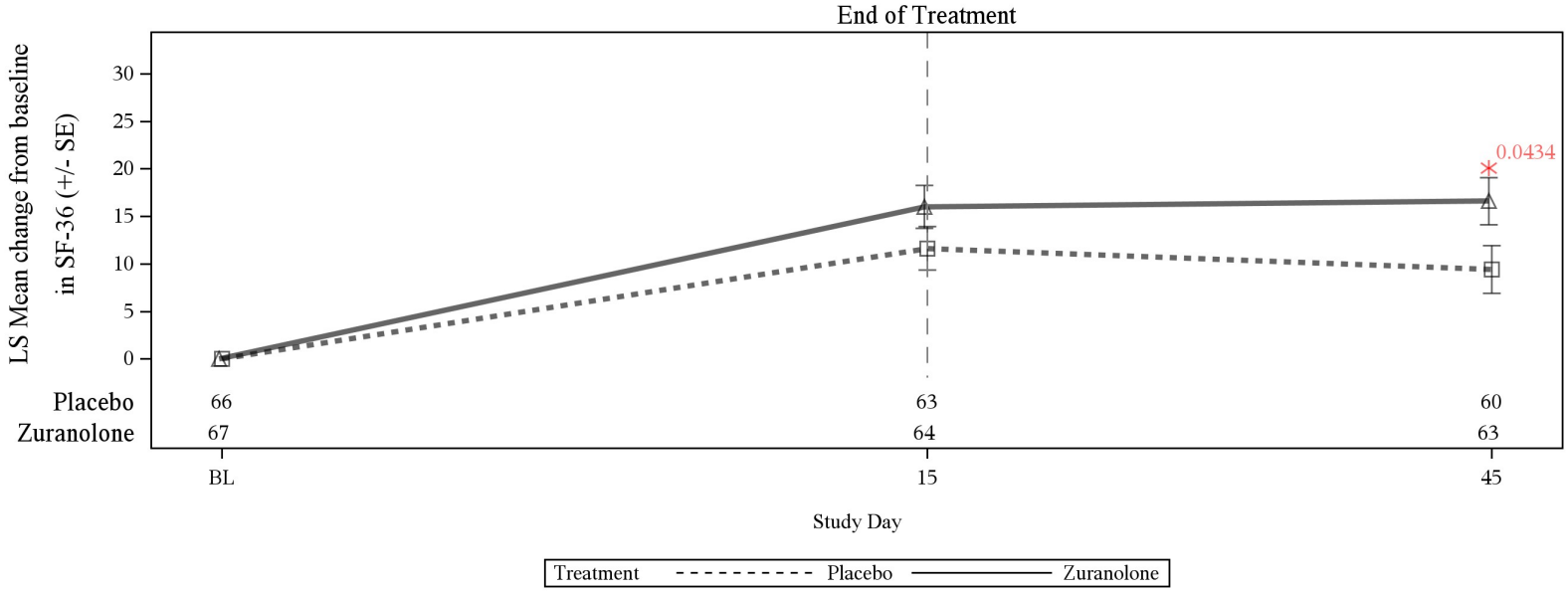
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

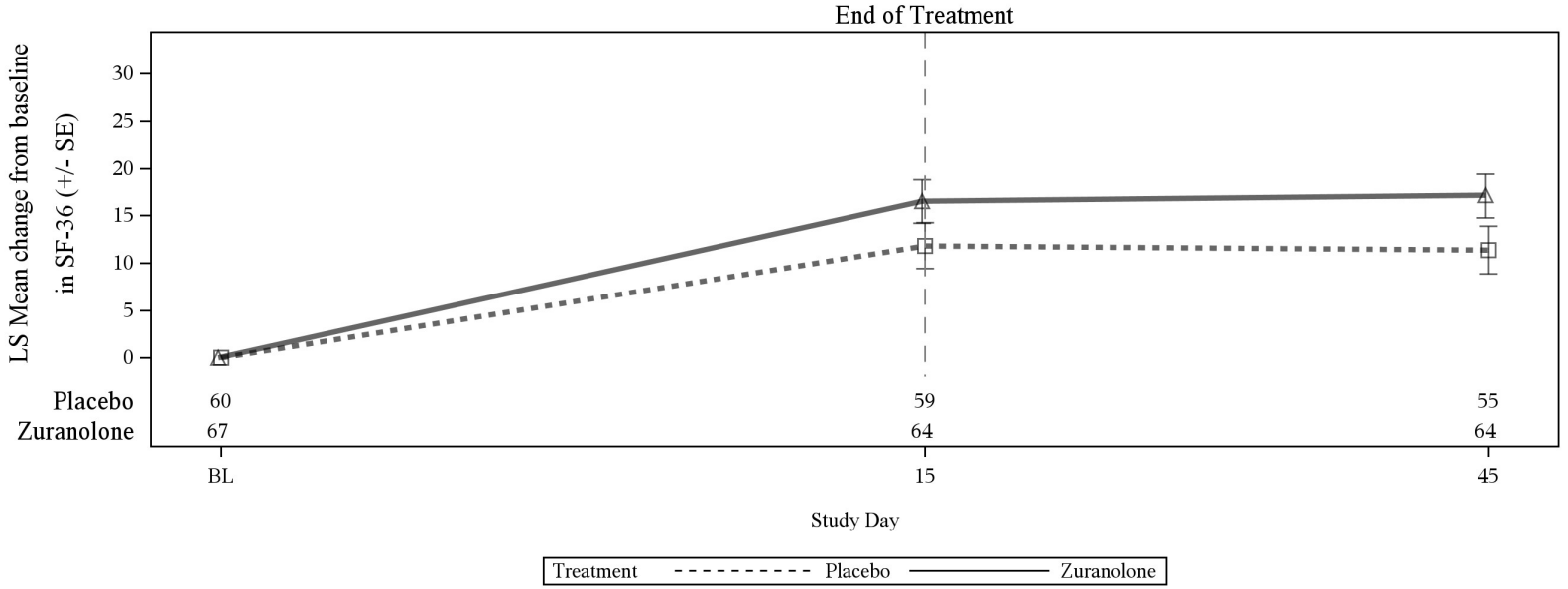
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Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

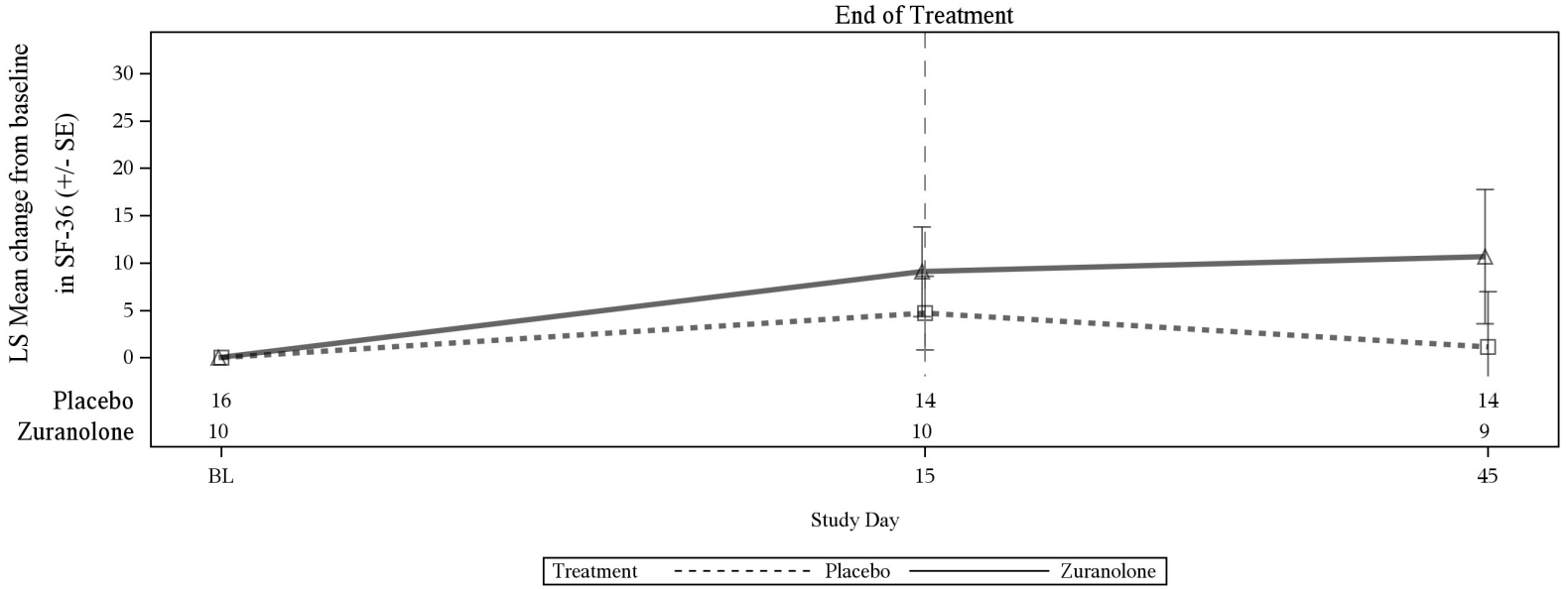
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Physical Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-pf-mmrm-201-by.sas:f-sf36-pf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

2.3.2 Ansprechen

2.3.2.1 Responder-Analysen

2.3.2.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with a response, n (%) [2]	25 (33.3)	32 (42.1)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.166
95% CI for the RR		(0.799, 1.701)
p-value for RR		0.4252
OR - Odds Ratio (Zuranolone vs. Placebo)		1.317
95% CI for the OR		(0.616, 2.817)
p-value for OR		0.4772
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.
[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-ovr.sas:t-sf36-pf-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	26 (34.7)	35 (46.1)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.226
95% CI for the RR		(0.847, 1.775)
p-value for RR		0.2796
OR - Odds Ratio (Zuranolone vs. Placebo)		1.525
95% CI for the OR		(0.705, 3.302)
p-value for OR		0.2839
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-ovr.sas:t-sf36-pf-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.3.2.1 .2 Subgruppen

2.3.2.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	25 (33.3)	32 (42.1)	
Number of subjects with response at Day 45, n (%)	26 (34.7)	35 (46.1)	
Age Group (years)			0.2524
Day 15			
18 - 24, n / N (%)	7/25 (28.0)	9/17 (52.9)	
25 - 45, n / N (%)	18/50 (36.0)	23/59 (39.0)	
Day 45			
18 - 24, n / N (%)	6/25 (24.0)	10/17 (58.8)	
25 - 45, n / N (%)	20/50 (40.0)	25/59 (42.4)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-int.sas:t-sf36-pf-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.3510
Day 15			
<28, n / N (%)	7/22 (31.8)	10/30 (33.3)	
>=28, n / N (%)	18/53 (34.0)	22/46 (47.8)	
Day 45			
<28, n / N (%)	8/22 (36.4)	13/30 (43.3)	
>=28, n / N (%)	18/53 (34.0)	22/46 (47.8)	
Race Group (Black or African American, White)			0.9487
Day 15			
Black or African American, n / N (%)	13/32 (40.6)	14/31 (45.2)	
White, n / N (%)	10/40 (25.0)	17/44 (38.6)	
Day 45			
Black or African American, n / N (%)	13/32 (40.6)	17/31 (54.8)	
White, n / N (%)	10/40 (25.0)	17/44 (38.6)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-int.sas:t-sf36-pf-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.2349
Day 15			
Yes, n / N (%)	1/13 (7.7)	6/16 (37.5)	
No, n / N (%)	24/62 (38.7)	26/60 (43.3)	
Day 45			
Yes, n / N (%)	5/13 (38.5)	6/16 (37.5)	
No, n / N (%)	21/62 (33.9)	29/60 (48.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-int.sas:t-sf36-pf-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.0760(a) 0.4006(b) 0.1730(c)
Day 15			
<=24.9, n / N (%)	6/21 (28.6)	5/13 (38.5)	
25-29.9, n / N (%)	9/20 (45.0)	10/21 (47.6)	
>=30, n / N (%)	10/34 (29.4)	17/42 (40.5)	
Day 45			
<=24.9, n / N (%)	5/21 (23.8)	6/13 (46.2)	
25-29.9, n / N (%)	10/20 (50.0)	10/21 (47.6)	
>=30, n / N (%)	11/34 (32.4)	19/42 (45.2)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-int.sas:t-sf36-pf-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 5 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.0777
Day 15			
3rd Trimester, n / N (%)	9/32 (28.1)	15/32 (46.9)	
Postpartum, n / N (%)	16/43 (37.2)	17/44 (38.6)	
Day 45			
3rd Trimester, n / N (%)	7/32 (21.9)	17/32 (53.1)	
Postpartum, n / N (%)	19/43 (44.2)	18/44 (40.9)	
Family History of PPD			0.2935
Day 15			
Yes, n / N (%)	1/10 (10.0)	3/10 (30.0)	
No/Unknown, n / N (%)	24/65 (36.9)	29/66 (43.9)	
Day 45			
Yes, n / N (%)	2/10 (20.0)	4/10 (40.0)	
No/Unknown, n / N (%)	24/65 (36.9)	31/66 (47.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-int.sas:t-sf36-pf-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.4105
Day 15			
1st Episode, n / N (%)	19/59 (32.2)	31/66 (47.0)	
Recurrent Episode, n / N (%)	6/16 (37.5)	1/10 (10.0)	
Day 45			
1st Episode, n / N (%)	21/59 (35.6)	33/66 (50.0)	
Recurrent Episode, n / N (%)	5/16 (31.3)	2/10 (20.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	2/8 (25.0)	3/10 (30.0)	
>=20, n / N (%)	23/67 (34.3)	29/66 (43.9)	
Day 45			
<20, n / N (%)	2/8 (25.0)	4/10 (40.0)	
>=20, n / N (%)	24/67 (35.8)	31/66 (47.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-int.sas:t-sf36-pf-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

2.3.2.1 .2 .2 Subgruppenanalysen

2.3.2.1 .2 .2 .1 Alter

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 15		
Number of subjects with a response, n (%) [2]	7 (28.0)	9 (52.9)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.402
95% CI for the RR		(0.747, 2.629)
p-value for RR		0.2926
Day 45		
Number of subjects with a response, n (%) [2]	6 (24.0)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.817
95% CI for the RR		(0.863, 3.828)
p-value for RR		0.1162

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 15		
Number of subjects with a response, n (%) [2]	18 (36.0)	23 (39.0)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.087
95% CI for the RR		(0.692, 1.708)
p-value for RR		0.7160
Day 45		
Number of subjects with a response, n (%) [2]	20 (40.0)	25 (42.4)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.064
95% CI for the RR		(0.699, 1.618)
p-value for RR		0.7725

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.3.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 15		
Number of subjects with a response, n (%) [2]	7 (31.8)	10 (33.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.857
95% CI for the RR		(0.409, 1.799)
p-value for RR		0.6836
Day 45		
Number of subjects with a response, n (%) [2]	8 (36.4)	13 (43.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.975
95% CI for the RR		(0.514, 1.851)
p-value for RR		0.9384

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 15		
Number of subjects with a response, n (%) [2]	18 (34.0)	22 (47.8)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.330
95% CI for the RR		(0.869, 2.035)
p-value for RR		0.1892
Day 45		
Number of subjects with a response, n (%) [2]	18 (34.0)	22 (47.8)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.330
95% CI for the RR		(0.854, 2.071)
p-value for RR		0.2075

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.3.2.1 .2 .2 .3 Abstammung

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 15		
Number of subjects with a response, n (%) [2]	13 (40.6)	14 (45.2)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.100
95% CI for the RR		(0.655, 1.846)
p-value for RR		0.7180
Day 45		
Number of subjects with a response, n (%) [2]	13 (40.6)	17 (54.8)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.336
95% CI for the RR		(0.804, 2.221)
p-value for RR		0.2642

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 15		
Number of subjects with a response, n (%) [2]	10 (25.0)	17 (38.6)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.185
95% CI for the RR		(0.642, 2.187)
p-value for RR		0.5877
Day 45		
Number of subjects with a response, n (%) [2]	10 (25.0)	17 (38.6)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.185
95% CI for the RR		(0.618, 2.273)
p-value for RR		0.6100

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.3.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 15		
Number of subjects with a response, n (%) [2]	1 (7.7)	6 (37.5)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		5.907
95% CI for the RR		(0.764, 45.658)
p-value for RR		0.0887
Day 45		
Number of subjects with a response, n (%) [2]	5 (38.5)	6 (37.5)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.181
95% CI for the RR		(0.527, 2.650)
p-value for RR		0.6861

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 15		
Number of subjects with a response, n (%) [2]	24 (38.7)	26 (43.3)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.012
95% CI for the RR		(0.687, 1.490)
p-value for RR		0.9537
Day 45		
Number of subjects with a response, n (%) [2]	21 (33.9)	29 (48.3)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.289
95% CI for the RR		(0.853, 1.950)
p-value for RR		0.2282

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.3.2.1 .2 .2 .5 BMI

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 15		
Number of subjects with a response, n (%) [2]	6 (28.6)	5 (38.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.590
95% CI for the RR		(0.686, 3.686)
p-value for RR		0.2794
Day 45		
Number of subjects with a response, n (%) [2]	5 (23.8)	6 (46.2)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.290
95% CI for the RR		(0.871, 6.020)
p-value for RR		0.0929

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 15		
Number of subjects with a response, n (%) [2]	9 (45.0)	10 (47.6)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.840
95% CI for the RR		(0.443, 1.593)
p-value for RR		0.5936
Day 45		
Number of subjects with a response, n (%) [2]	10 (50.0)	10 (47.6)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.756
95% CI for the RR		(0.437, 1.308)
p-value for RR		0.3174

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 15		
Number of subjects with a response, n (%) [2]	10 (29.4)	17 (40.5)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.313
95% CI for the RR		(0.747, 2.307)
p-value for RR		0.3439
Day 45		
Number of subjects with a response, n (%) [2]	11 (32.4)	19 (45.2)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.334
95% CI for the RR		(0.789, 2.255)
p-value for RR		0.2822

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.3.2.1 .2 .2 .6 Beginn der PPD

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 15		
Number of subjects with a response, n (%) [2]	9 (28.1)	15 (46.9)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.454
95% CI for the RR		(0.808, 2.616)
p-value for RR		0.2115
Day 45		
Number of subjects with a response, n (%) [2]	7 (21.9)	17 (53.1)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.119
95% CI for the RR		(1.061, 4.232)
p-value for RR		0.0334

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 15		
Number of subjects with a response, n (%) [2]	16 (37.2)	17 (38.6)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.997
95% CI for the RR		(0.611, 1.628)
p-value for RR		0.9917
Day 45		
Number of subjects with a response, n (%) [2]	19 (44.2)	18 (40.9)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.889
95% CI for the RR		(0.566, 1.396)
p-value for RR		0.6104

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.3.2.1 .2 .2 .7 PPD in der Familie

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 15		
Number of subjects with a response, n (%) [2]	1 (10.0)	3 (30.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.250
95% CI for the RR		(0.291, 17.413)
p-value for RR		0.4372
Day 45		
Number of subjects with a response, n (%) [2]	2 (20.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.500
95% CI for the RR		(0.294, 7.654)
p-value for RR		0.6257

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 15		
Number of subjects with a response, n (%) [2]	24 (36.9)	29 (43.9)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.077
95% CI for the RR		(0.740, 1.567)
p-value for RR		0.6984
Day 45		
Number of subjects with a response, n (%) [2]	24 (36.9)	31 (47.0)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.151
95% CI for the RR		(0.788, 1.682)
p-value for RR		0.4666

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Physical Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.3.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 15		
Number of subjects with a response, n (%) [2]	19 (32.2)	31 (47.0)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.46
95% CI for the RR		(0.930, 2.288)
p-value for RR		0.1004
Day 45		
Number of subjects with a response, n (%) [2]	21 (35.6)	33 (50.0)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.40
95% CI for the RR		(0.923, 2.137)
p-value for RR		0.1123

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 15		
Number of subjects with a response, n (%) [2]	6 (37.5)	1 (10.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.27
95% CI for the RR		(0.037, 1.901)
p-value for RR		0.1872
Day 45		
Number of subjects with a response, n (%) [2]	5 (31.3)	2 (20.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.64
95% CI for the RR		(0.152, 2.693)
p-value for RR		0.5427

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Physical Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

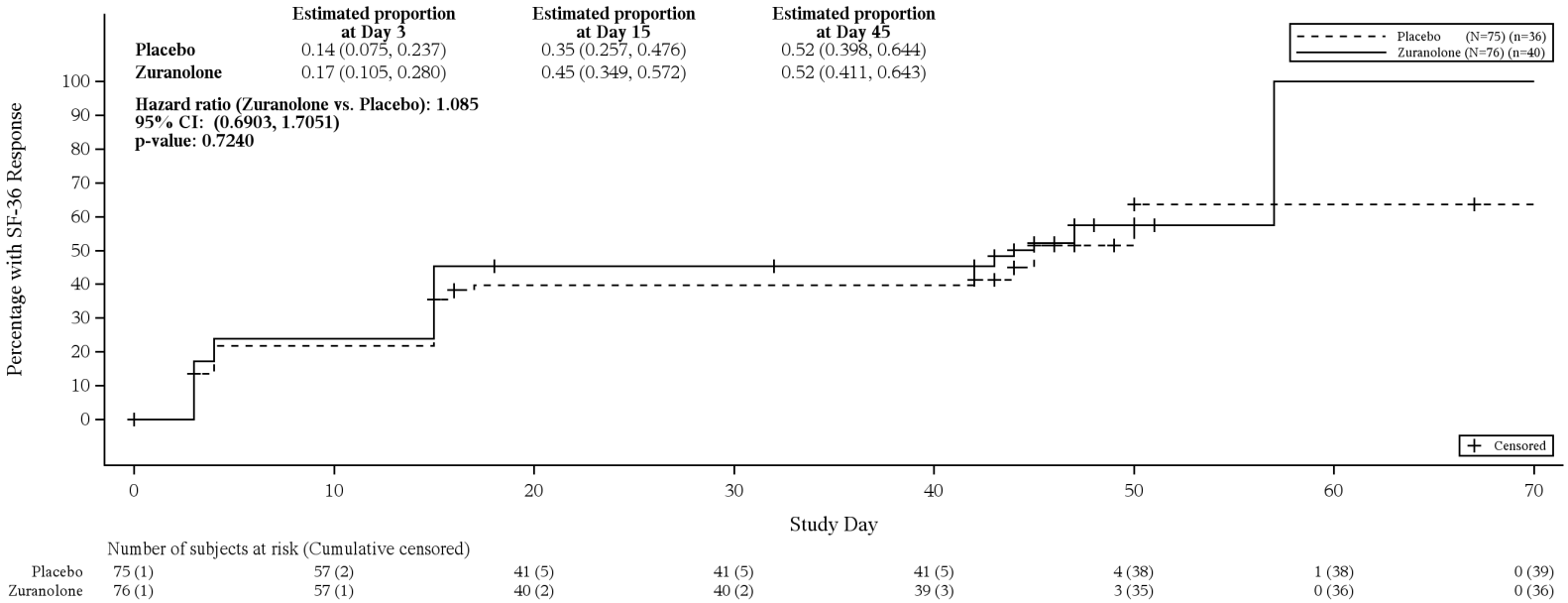
Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-201-by.sas:t-sf36-pf-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.3.2.2 TTE-Analysen

2.3.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-pf-resp15-tte-201-ovr.sas:f-sf36-pf-resp15-tte-201-ovr-itta.rtf **Run Date:** 15DEC2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	36 (48.0)	40 (52.6)
Time to first SF-36 Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (16.0, NE)	44.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	57.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.085
95% CI for the HR		(0.6903 , 1.7051)
p-value for the HR		0.7240

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-ovr.sas:t-sf36-pf-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.3.2.2 .2 Subgruppen

2.3.2.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	36 (48.0)	40 (52.6)	
Age Group (years)			
18 - 24, n / N (%)	11/25 (44.0)	11/17 (64.7)	0.8086
25 - 45, n / N (%)	25/50 (50.0)	29/59 (49.2)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	10/22 (45.5)	14/30 (46.7)	0.2291
>=28, n / N (%)	26/53 (49.1)	26/46 (56.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	21/32 (65.6)	18/31 (58.1)	0.0631
White, n / N (%)	12/40 (30.0)	21/44 (47.7)	
Antidepressant Use at Baseline			
Yes, n / N (%)	5/13 (38.5)	6/16 (37.5)	0.4955
No, n / N (%)	31/62 (50.0)	34/60 (56.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-int.sas:t-sf36-pf-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	8/21 (38.1)	6/13 (46.2)	0.2399(a)
25-29.9, n / N (%)	11/20 (55.0)	13/21 (61.9)	0.1570(b)
>=30, n / N (%)	17/34 (50.0)	21/42 (50.0)	0.8711(c)
Onset of PPD			
3rd Trimester, n / N (%)	12/32 (37.5)	19/32 (59.4)	0.4824
Postpartum, n / N (%)	24/43 (55.8)	21/44 (47.7)	
Family History of PPD			
Yes, n / N (%)	3/10 (30.0)	4/10 (40.0)	0.6864
No/Unknown, n / N (%)	33/65 (50.8)	36/66 (54.5)	
History of PPD			
1st Episode, n / N (%)	29/59 (49.2)	37/66 (56.1)	0.5118
Recurrent Episode, n / N (%)	7/16 (43.8)	3/10 (30.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	2/8 (25.0)	5/10 (50.0)	NA
>=20, n / N (%)	34/67 (50.7)	35/66 (53.0)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-int.sas:t-sf36-pf-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.3.2.2 .2 .2 Subgruppenanalysen

2.3.2.2 .2 .2 .1 Alter

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	11 (44.0)	11 (64.7)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 44.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	NE (15.0, NE)	15.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.967
95% CI for the HR		(0.4014 , 2.3311)
p-value for the HR		0.9409

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	25 (50.0)	29 (49.2)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	57.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	57.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.110
95% CI for the HR		(0.6449 , 1.9108)
p-value for the HR		0.7062

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.3.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	10 (45.5)	14 (46.7)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 44.0)	15.0 (4.0 , 44.0)
50th percentile - median (95% CI)	NE (15.0, NE)	57.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	57.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.750
95% CI for the HR		(0.3198 , 1.7574)
p-value for the HR		0.5074

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	26 (49.1)	26 (56.5)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 16.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (16.0, NE)	15.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	NE (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.337
95% CI for the HR		(0.7711 , 2.3183)
p-value for the HR		0.3010

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.3.2.2 .2 .2 .3 Abstammung

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	21 (65.6)	18 (58.1)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 44.0)	45.0 (15.0, NE)
75th percentile - Q3 (95% CI)	50.0 (42.0, NE)	57.0 (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.629
95% CI for the HR		(0.3251 , 1.2185)
p-value for the HR		0.1696

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	12 (30.0)	21 (47.7)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	17.0 (15.0, NE)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	NE (45.0, NE)	44.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.557
95% CI for the HR		(0.7614 , 3.1830)
p-value for the HR		0.2252

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.3.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	5 (38.5)	6 (37.5)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	45.0 (3.0 , 50.0)	15.0 (3.0, NE)
50th percentile - median (95% CI)	50.0 (42.0, NE)	NE (15.0, NE)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.342
95% CI for the HR		(0.7328 , 15.2442)
p-value for the HR		0.1191

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	31 (50.0)	34 (56.7)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	44.0 (15.0, NE)	43.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	57.0 (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.028
95% CI for the HR		(0.6313 , 1.6752)
p-value for the HR		0.9105

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.3.2.2 .2 .2 .5 BMI

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	8 (38.1)	6 (46.2)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 45.0)	15.0 (3.0 , 47.0)
50th percentile - median (95% CI)	NE (15.0, NE)	47.0 (4.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.133
95% CI for the HR		(0.6744 , 6.7443)
p-value for the HR		0.1973

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	11 (55.0)	13 (61.9)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 16.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (4.0, NE)	15.0 (4.0, NE)
75th percentile - Q3 (95% CI)	50.0 (45.0, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.983
95% CI for the HR		(0.4186 , 2.3066)
p-value for the HR		0.9679

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	17 (50.0)	21 (50.0)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 17.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	44.0 (15.0, NE)	57.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	57.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.847
95% CI for the HR		(0.4425 , 1.6199)
p-value for the HR		0.6150

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.3.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	12 (37.5)	19 (59.4)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 45.0)	3.5 (3.0 , 15.0)
50th percentile - median (95% CI)	NE (15.0, NE)	29.0 (4.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	57.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.322
95% CI for the HR		(0.6351 , 2.7518)
p-value for the HR		0.4554

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	24 (55.8)	21 (47.7)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	44.0 (15.0, NE)	47.0 (15.0, NE)
75th percentile - Q3 (95% CI)	50.0 (50.0, NE)	NE (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.941
95% CI for the HR		(0.5204 , 1.7025)
p-value for the HR		0.8413

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.3.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	3 (30.0)	4 (40.0)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	45.0 (3.0, NE)	15.0 (15.0, NE)
50th percentile - median (95% CI)	NE (3.0, NE)	NE (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.223
95% CI for the HR		(0.2605 , 5.7439)
p-value for the HR		0.7984

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	33 (50.8)	36 (54.5)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	44.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	57.0 (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.037
95% CI for the HR		(0.6435 , 1.6706)
p-value for the HR		0.8818

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.3.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	29 (49.2)	37 (56.1)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 17.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (17.0, NE)	43.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	NE (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.153
95% CI for the HR		(0.7048 , 1.8847)
p-value for the HR		0.5715

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	7 (43.8)	3 (30.0)
Time to first Physical Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	57.0 (4.0, NE)
50th percentile - median (95% CI)	NE (3.0, NE)	57.0 (4.0, NE)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	57.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.775
95% CI for the HR		(0.1287 , 4.6645)
p-value for the HR		0.7805

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

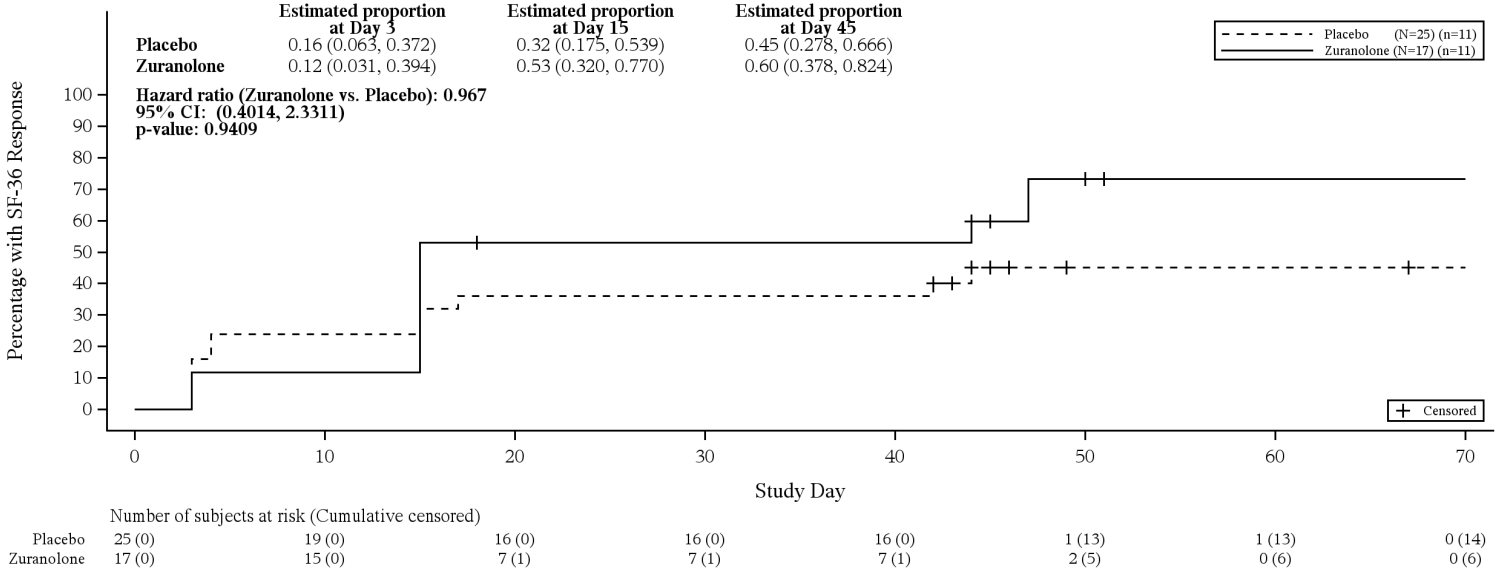
Source: biib125/v_a/germany_amnog/t-sf36-pf-resp15-tte-201-by.sas:t-sf36-pf-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.3.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

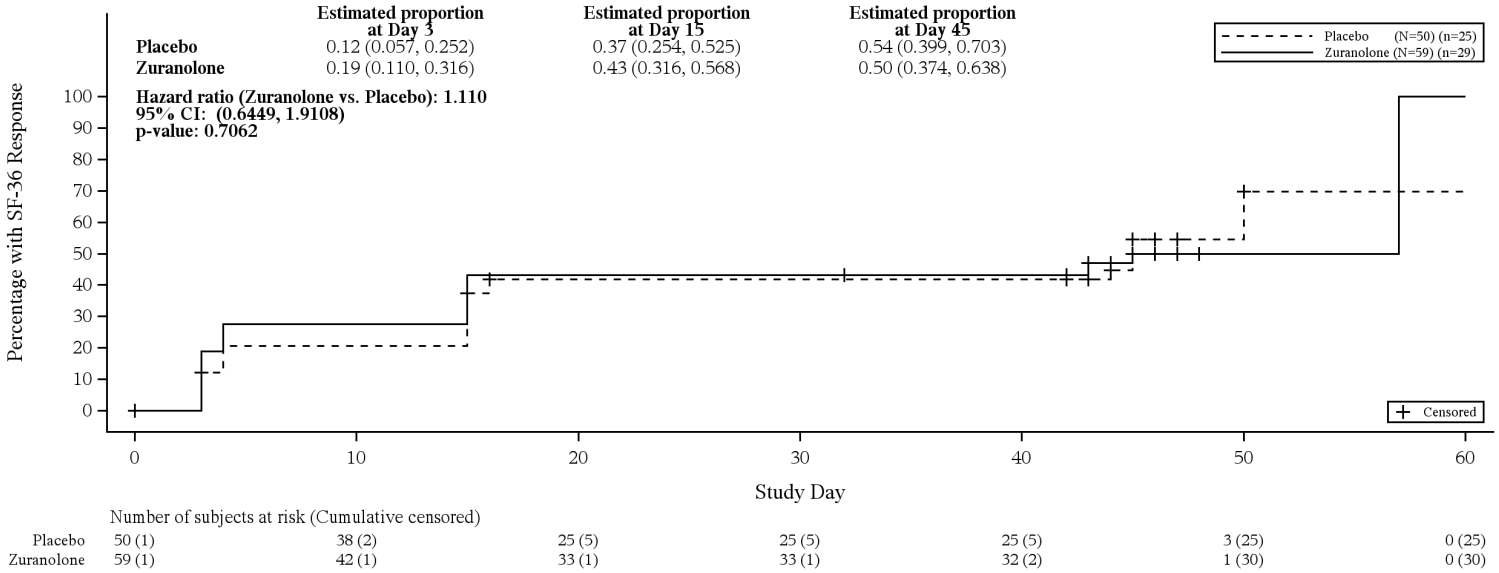
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-pf-resp15-tte-201-by.sas:f-sf36-pf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

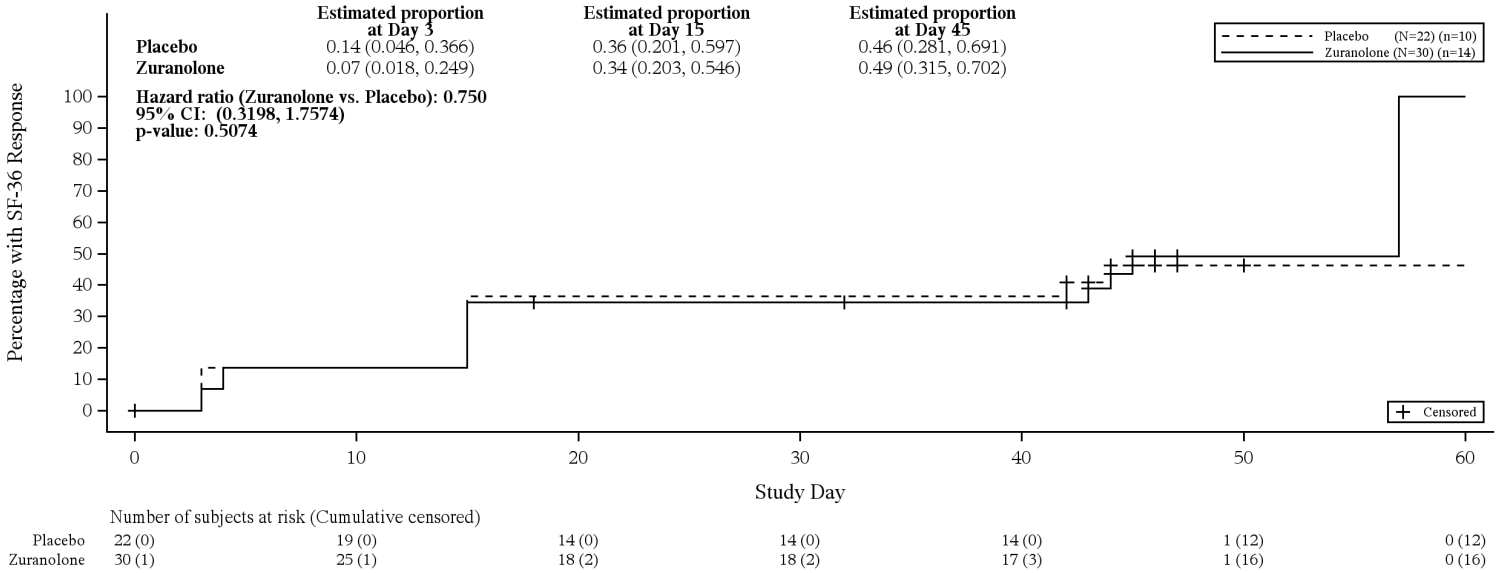
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

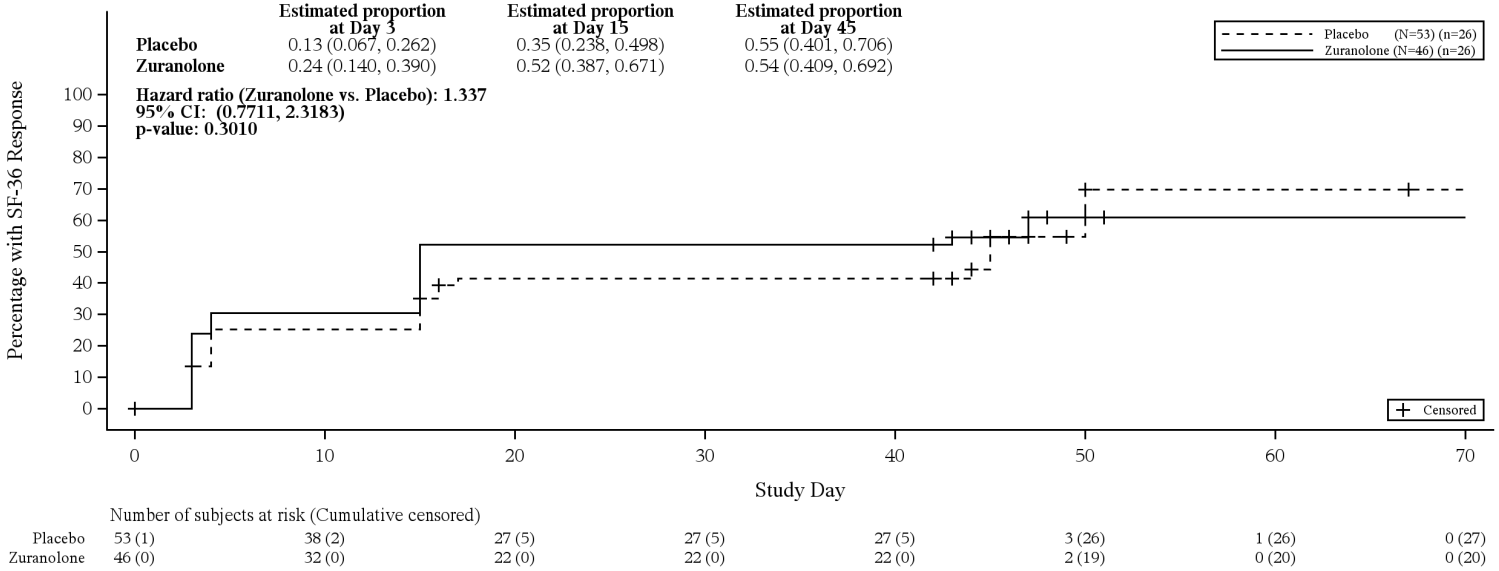
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

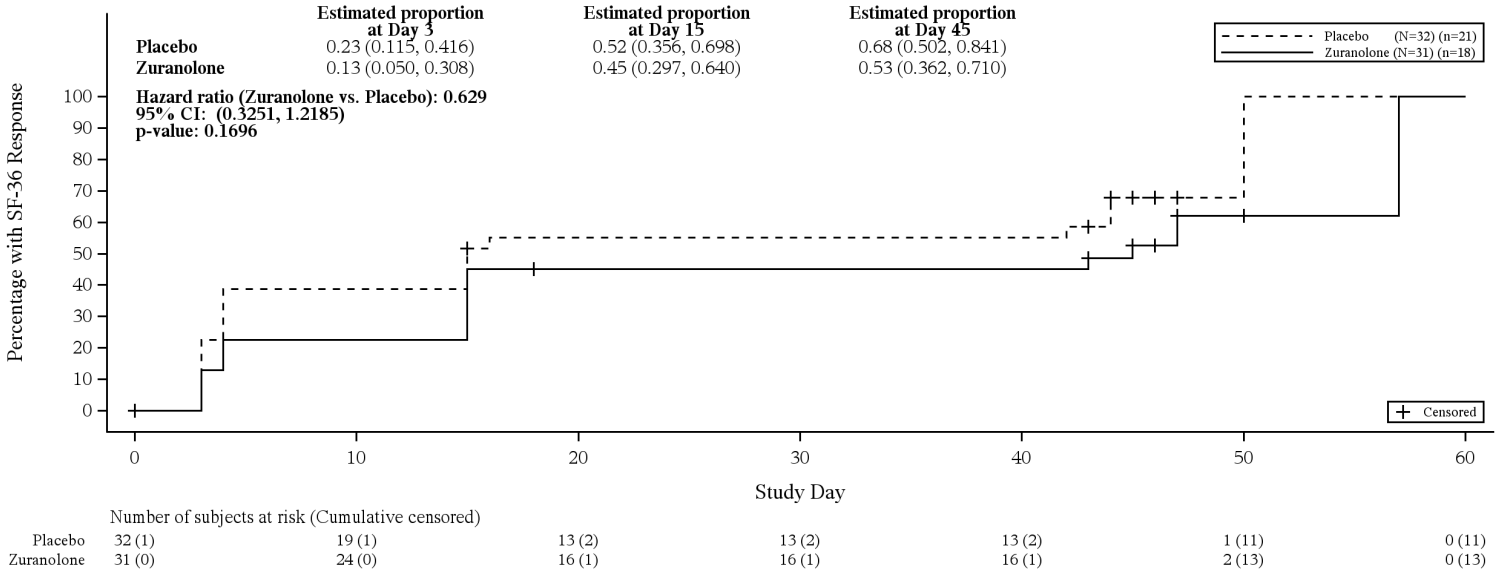
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

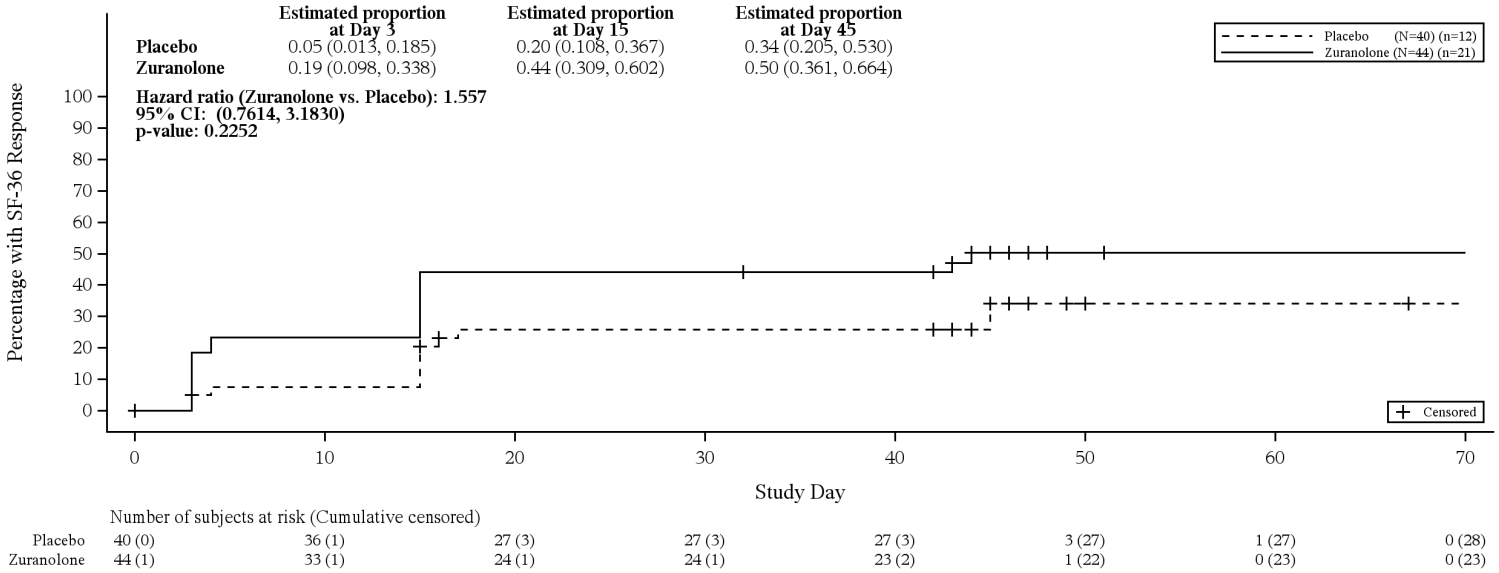
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

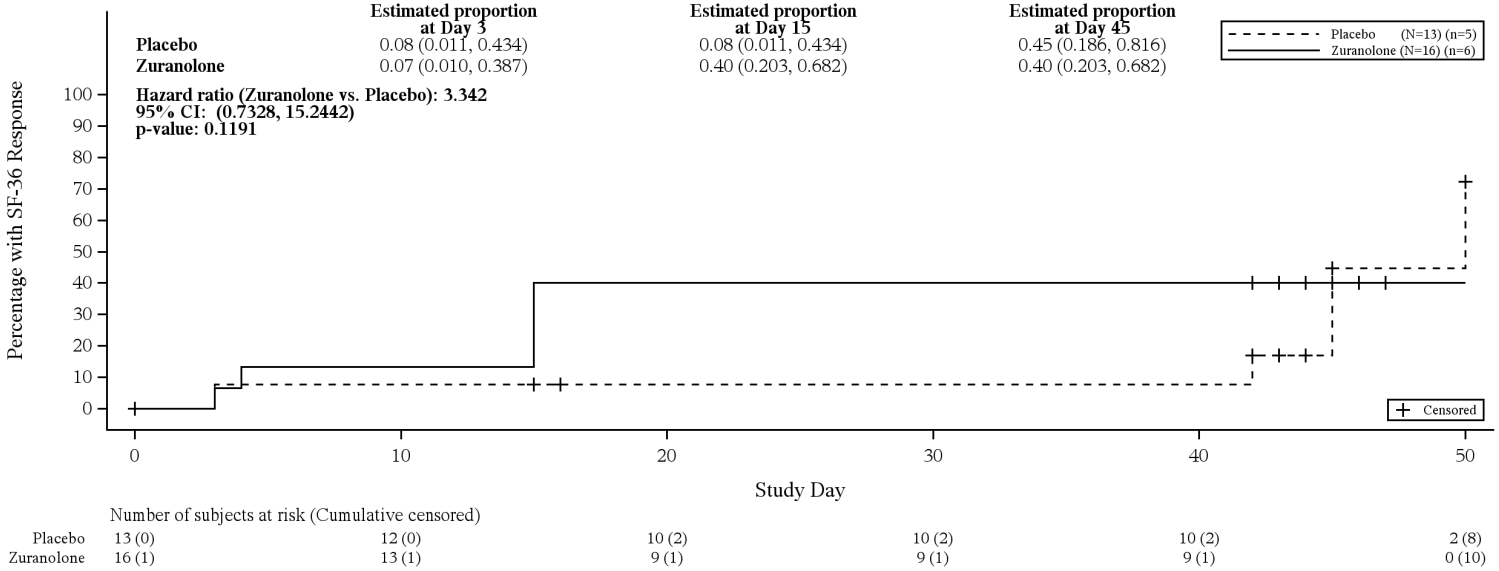
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 7 of 17

Antidepressant Use at Baseline = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

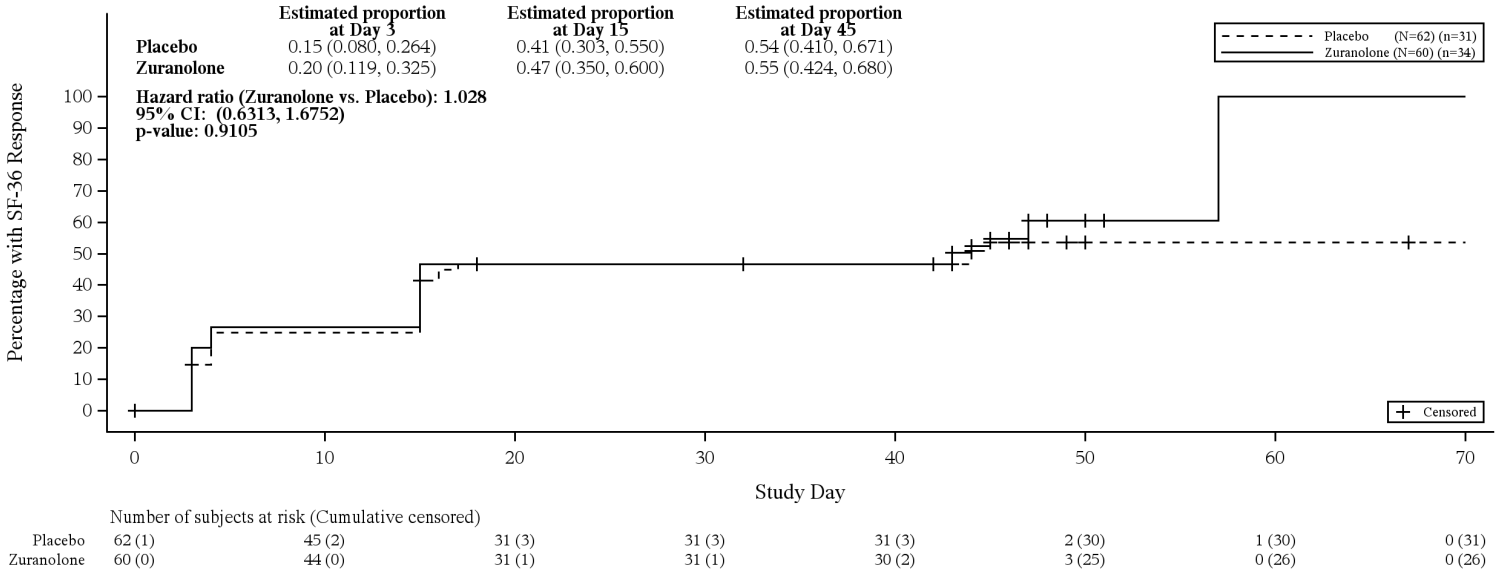
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

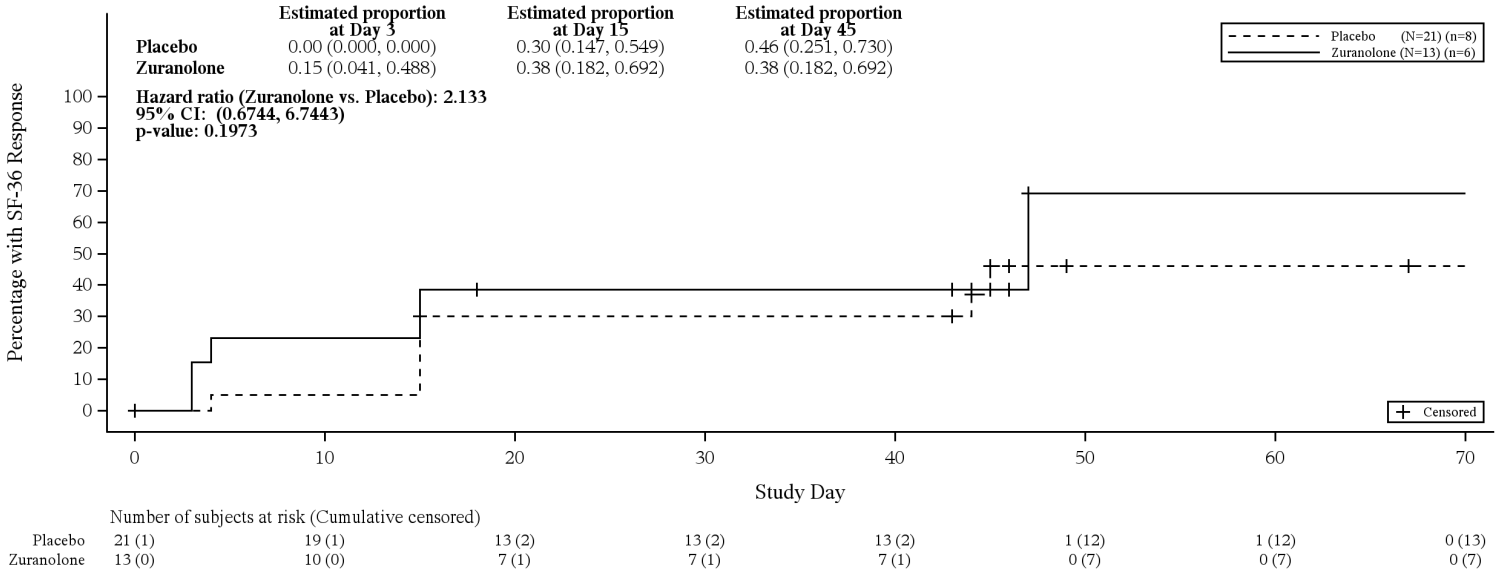
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

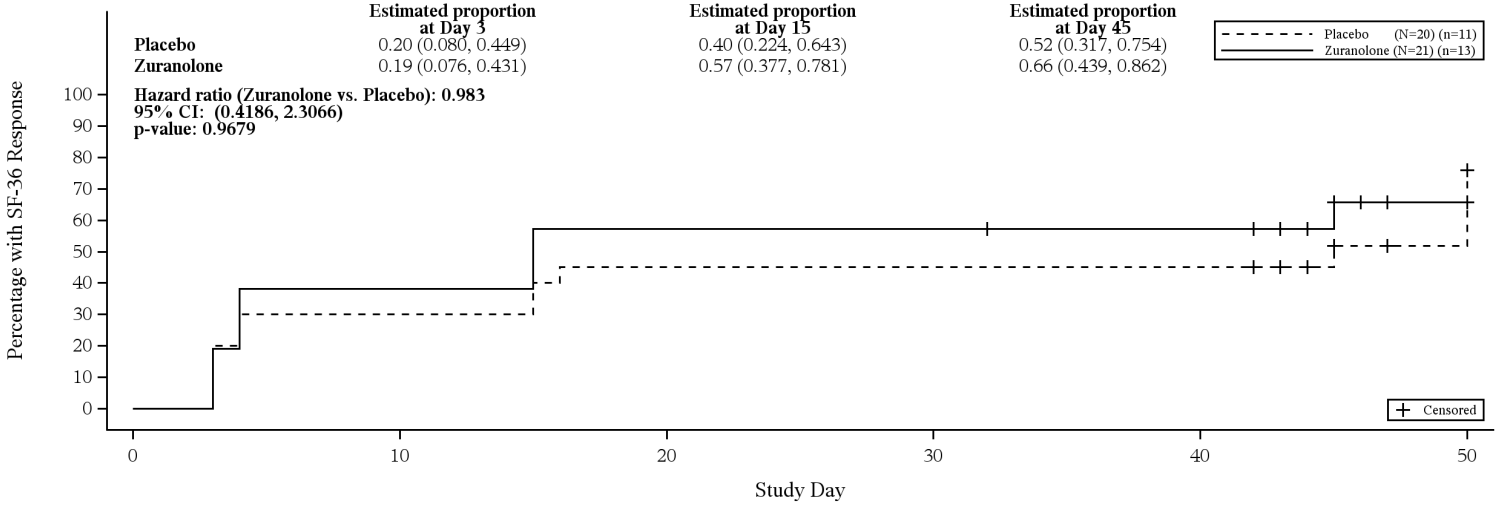
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

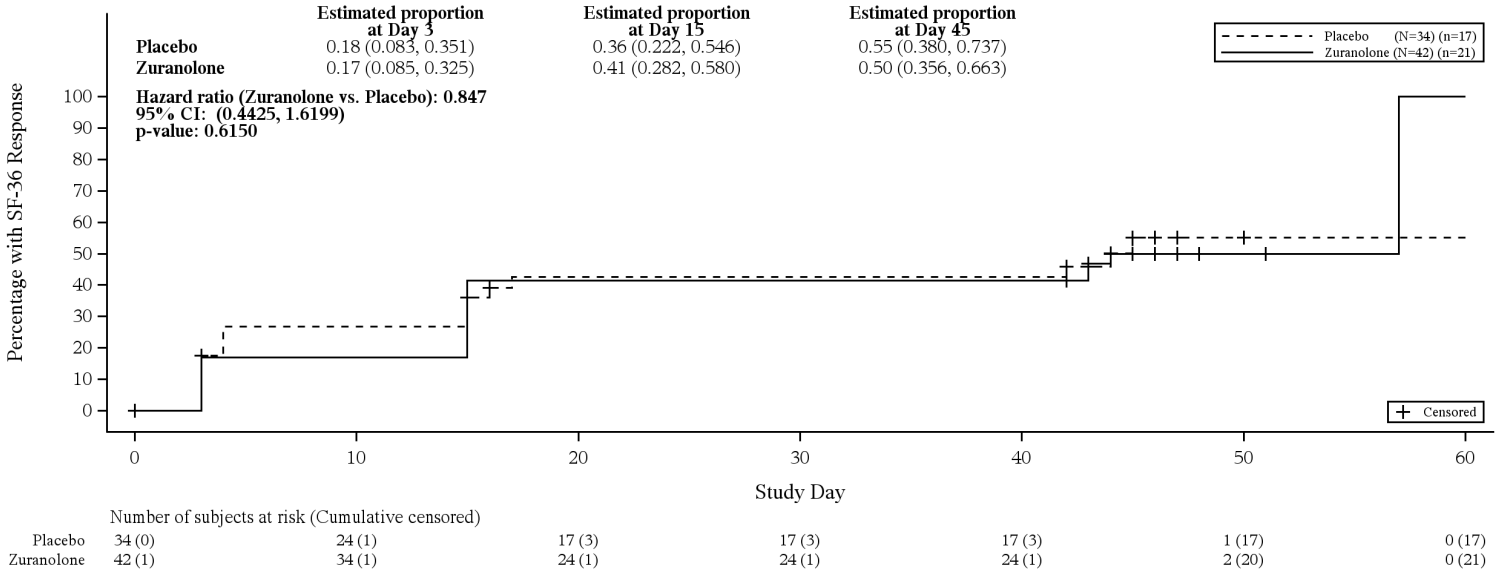
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

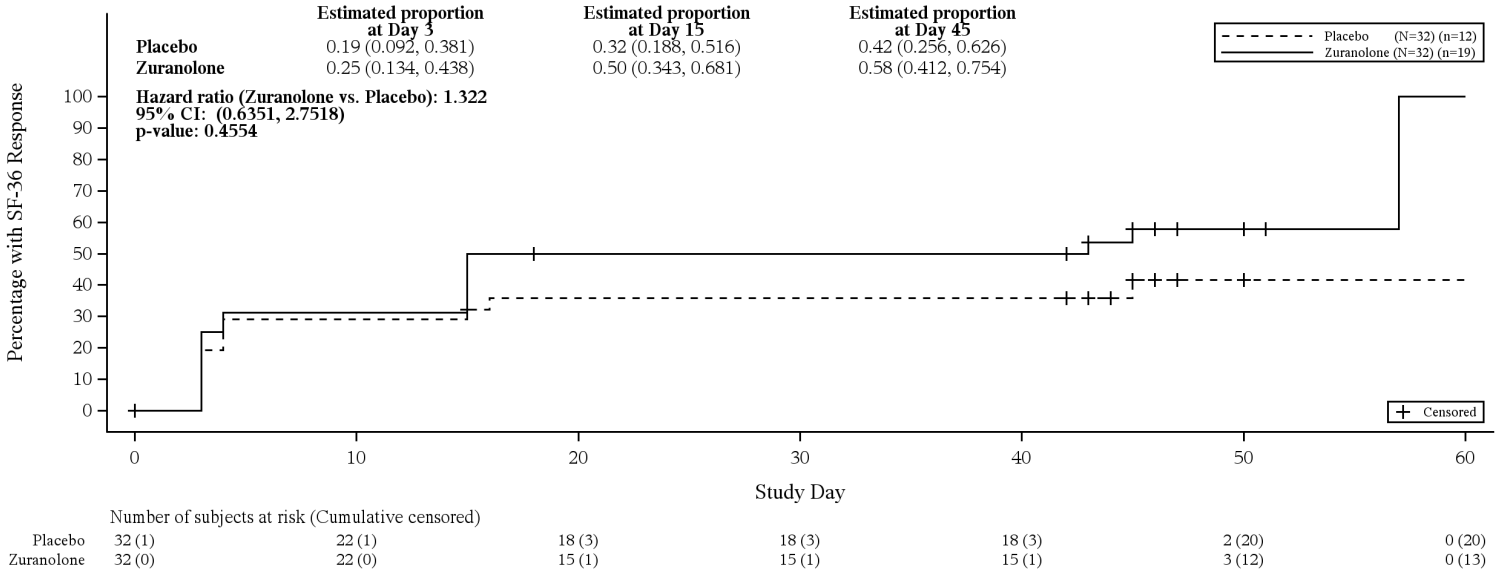
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

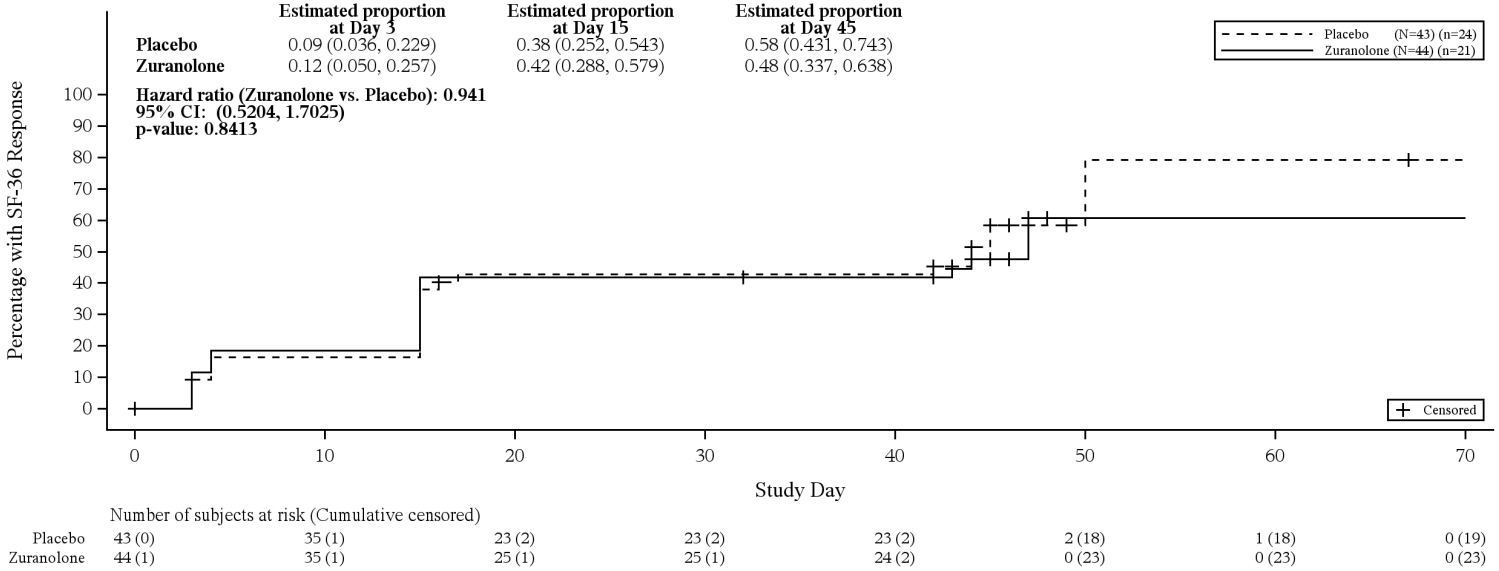
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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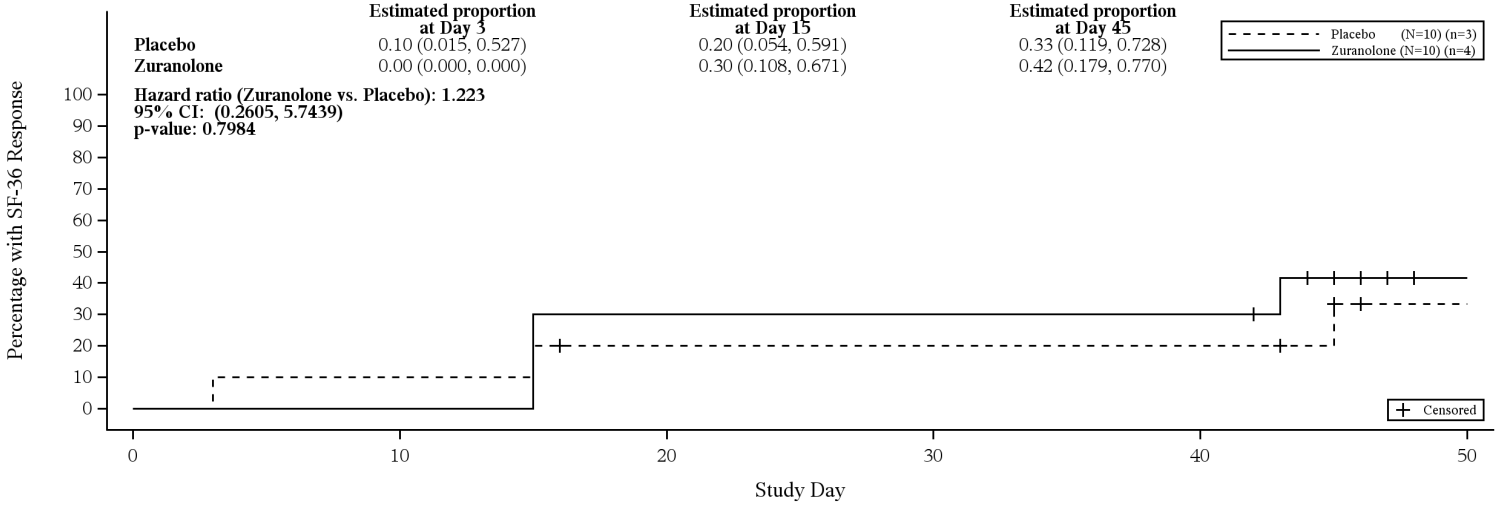
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Number of subjects at risk (Cumulative censored)

Placebo	10 (0)	9 (0)	7 (1)	7 (1)	7 (1)	0 (7)
Zuranolone	10 (0)	10 (0)	7 (0)	7 (0)	7 (0)	0 (6)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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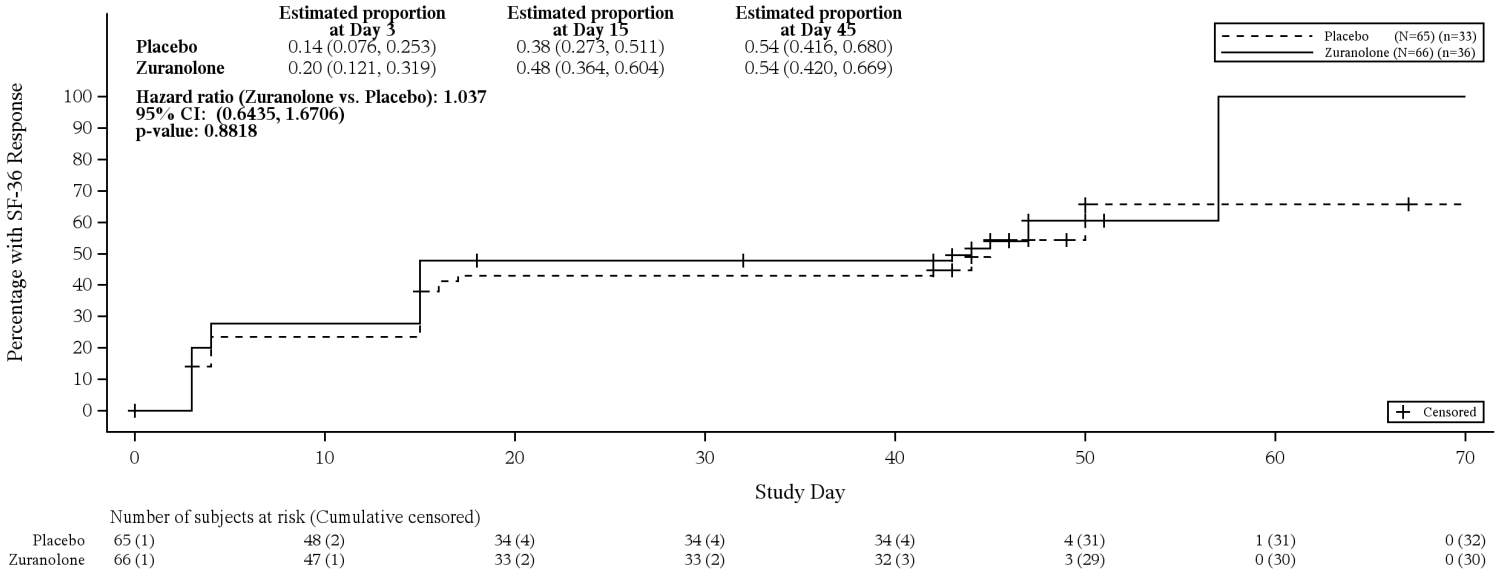
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 15 of 17

Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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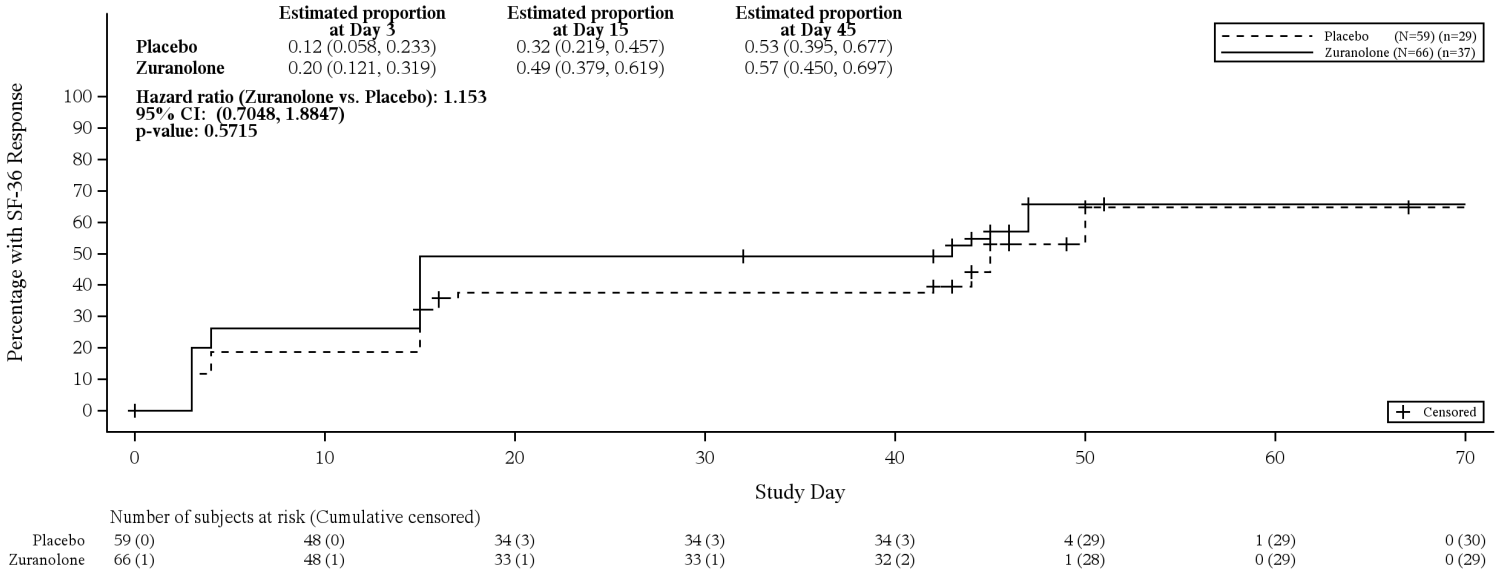
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 16 of 17

History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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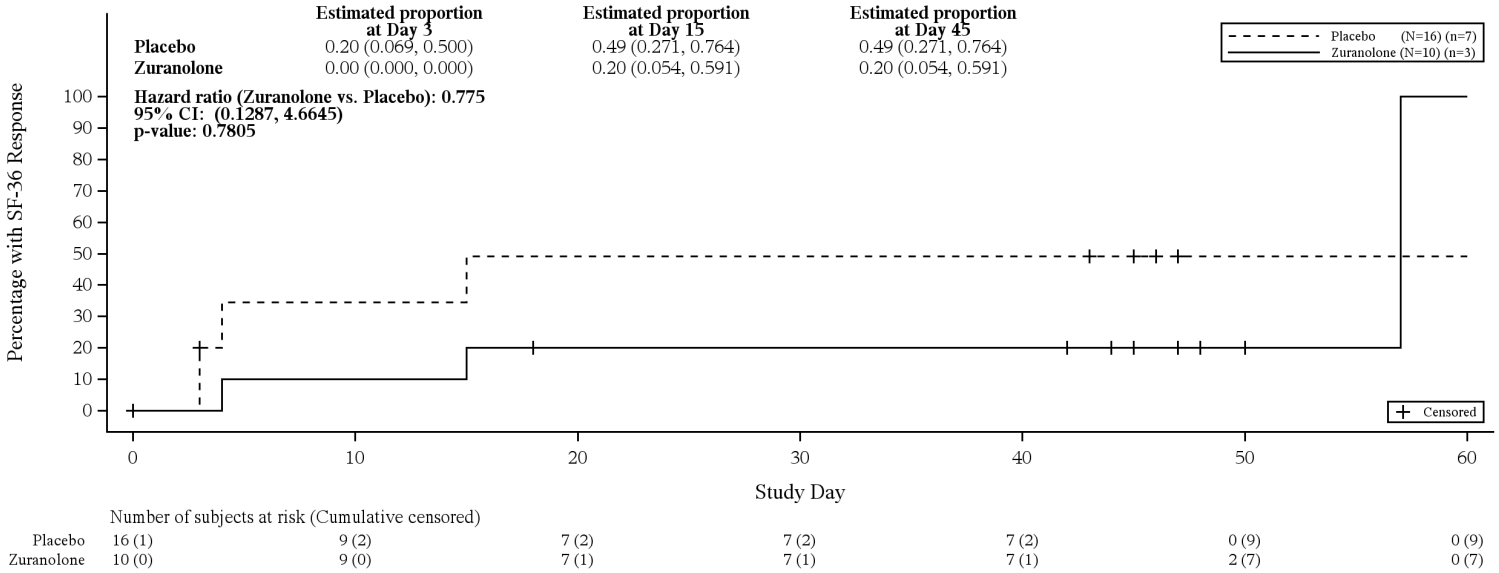
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-pf-resp15-tte-201-by.sas:f-sf36-pf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 17 of 17

History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-pf-resp15-tte-201-by.sas:f-sf36-pf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

2.3.3 Verschlechterung

2.3.3.1 Responder-Analysen

2.3.3.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with worsening, n (%) [2]	5 (6.7)	2 (2.6)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.39
95% CI for the RR		(0.079, 1.972)
p-value for RR		0.2574
OR - Odds Ratio (Zuranolone vs. Placebo)		0.38
95% CI for the OR		(0.071, 2.014)
p-value for OR		0.2546
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.04
95% CI for the ARR		(-0.107, 0.027)
p-value for ARR		0.2375

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Functioning subscale score worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-pf-wors15-201-ovr.sas:t-sf36-pf-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	4 (5.3)	4 (5.3)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.99
95% CI for the RR		(0.256, 3.802)
p-value for RR		0.9846
OR - Odds Ratio (Zuranolone vs. Placebo)		0.99
95% CI for the OR		(0.237, 4.097)
p-value for OR		0.9846
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.072, 0.071)
p-value for ARR		0.9846

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing SF-36 Physical Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Physical Functioning subscale score worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-pf-wors15-201-ovr.sas:t-sf36-pf-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.3.3.1 .2 Subgruppen

2.3.3.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	5 (6.7)	2 (2.6)	
Number of subjects with response at Day 45, n (%)	4 (5.3)	4 (5.3)	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	0/25	1/17 (5.9)	
25 - 45, n / N (%)	5/50 (10.0)	1/59 (1.7)	
Day 45			
18 - 24, n / N (%)	1/25 (4.0)	0/17	
25 - 45, n / N (%)	3/50 (6.0)	4/59 (6.8)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-wors15-201-int.sas:t-sf36-pf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	0/22	1/30 (3.3)	
>=28, n / N (%)	5/53 (9.4)	1/46 (2.2)	
Day 45			
<28, n / N (%)	2/22 (9.1)	1/30 (3.3)	
>=28, n / N (%)	2/53 (3.8)	3/46 (6.5)	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	4/32 (12.5)	1/31 (3.2)	
White, n / N (%)	1/40 (2.5)	1/44 (2.3)	
Day 45			
Black or African American, n / N (%)	3/32 (9.4)	1/31 (3.2)	
White, n / N (%)	1/40 (2.5)	3/44 (6.8)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-wors15-201-int.sas:t-sf36-pf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	5/62 (8.1)	2/60 (3.3)	
Day 45			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	4/62 (6.5)	4/60 (6.7)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-wors15-201-int.sas:t-sf36-pf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 4 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	0/21	0/13	
25-29.9, n / N (%)	2/20 (10.0)	0/21	
>=30, n / N (%)	3/34 (8.8)	2/42 (4.8)	
Day 45			
<=24.9, n / N (%)	2/21 (9.5)	0/13	
25-29.9, n / N (%)	1/20 (5.0)	2/21 (9.5)	
>=30, n / N (%)	1/34 (2.9)	2/42 (4.8)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-wors15-201-int.sas:t-sf36-pf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	3/32 (9.4)	1/32 (3.1)	
Postpartum, n / N (%)	2/43 (4.7)	1/44 (2.3)	
Day 45			
3rd Trimester, n / N (%)	2/32 (6.3)	1/32 (3.1)	
Postpartum, n / N (%)	2/43 (4.7)	3/44 (6.8)	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	5/65 (7.7)	2/66 (3.0)	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	4/65 (6.2)	4/66 (6.1)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-wors15-201-int.sas:t-sf36-pf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Physical Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	3/59 (5.1)	2/66 (3.0)	
Recurrent Episode, n / N (%)	2/16 (12.5)	0/10	
Day 45			
1st Episode, n / N (%)	3/59 (5.1)	4/66 (6.1)	
Recurrent Episode, n / N (%)	1/16 (6.3)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	5/67 (7.5)	2/66 (3.0)	
Day 45			
<20, n / N (%)	1/8 (12.5)	1/10 (10.0)	
>=20, n / N (%)	3/67 (4.5)	3/66 (4.5)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-wors15-201-int.sas:t-sf36-pf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

2.3.3.1 .2 .2 Subgruppenanalysen

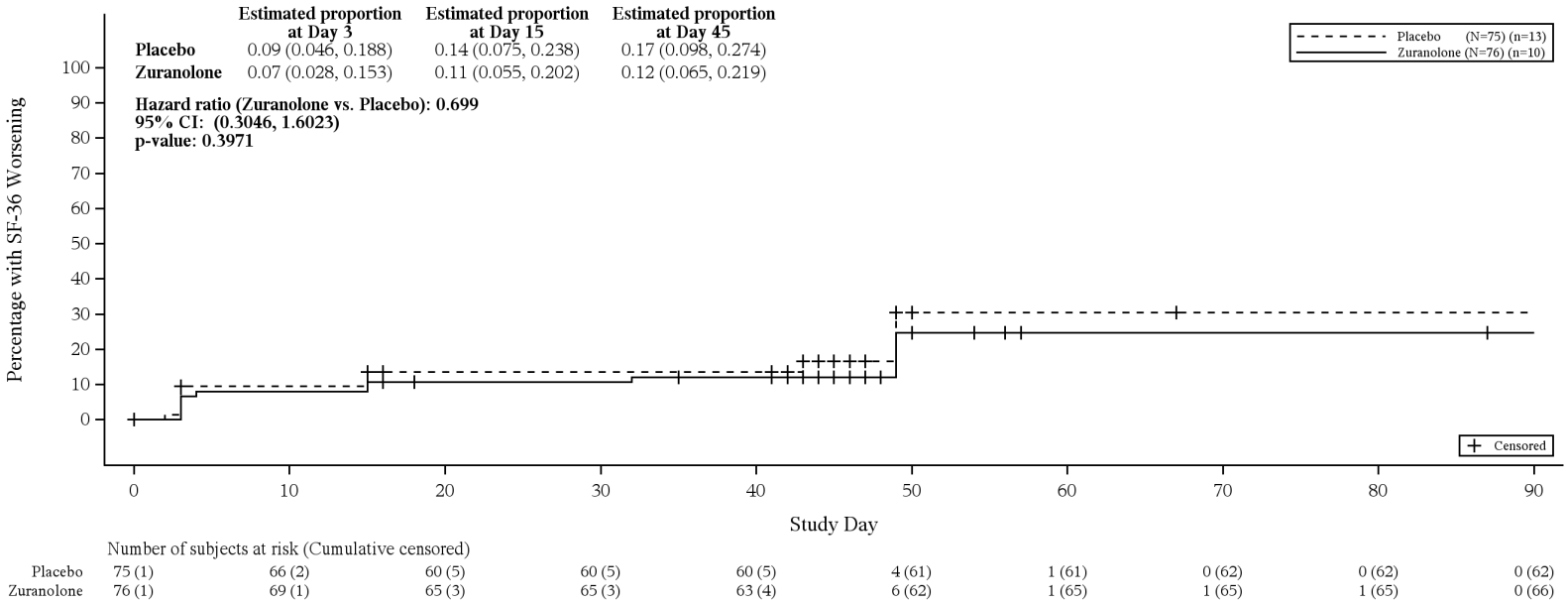
Nicht zutreffend.

2.3.3.2 TTE-Analysen

2.3.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-pf-wors15-tte-201-ovr.sas:f-sf36-pf-wors15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	13 (17.3)	10 (13.2)
Time to first Physical Functioning Subscale worsening (days) [3]		
25th percentile - Q1 (95% CI)	49.0 (43.0, NE)	NE (49.0, NE)
50th percentile - median (95% CI)	NE (49.0, NE)	NE (49.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.699
95% CI for the HR		(0.3046 , 1.6023)
p-value for the HR		0.3971

NOTE 1: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) worsening. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-pf-wors15-tte-201-ovr.sas:t-sf36-pf-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.3.3.2 .2 Subgruppen

2.3.3.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	13 (17.3)	10 (13.2)	
Age Group (years)			
18 - 24, n / N (%)	2/25 (8.0)	3/17 (17.6)	0.2060
25 - 45, n / N (%)	11/50 (22.0)	7/59 (11.9)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	3/22 (13.6)	4/30 (13.3)	0.5850
>=28, n / N (%)	10/53 (18.9)	6/46 (13.0)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	11/32 (34.4)	3/31 (9.7)	0.0063
White, n / N (%)	2/40 (5.0)	7/44 (15.9)	
Antidepressant Use at Baseline			
Yes, n / N (%)	0/13	1/16 (6.3)	0.9905
No, n / N (%)	13/62 (21.0)	9/60 (15.0)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-wors15-tte-201-int.sas:t-sf36-pf-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Physical Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	5/21 (23.8)	0/13	NA(a)
25-29.9, n / N (%)	3/20 (15.0)	3/21 (14.3)	NA(b)
>=30, n / N (%)	5/34 (14.7)	7/42 (16.7)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	6/32 (18.8)	5/32 (15.6)	NA
Postpartum, n / N (%)	7/43 (16.3)	5/44 (11.4)	
Family History of PPD			
Yes, n / N (%)	1/10 (10.0)	0/10	0.9925
No/Unknown, n / N (%)	12/65 (18.5)	10/66 (15.2)	
History of PPD			
1st Episode, n / N (%)	9/59 (15.3)	10/66 (15.2)	0.9912
Recurrent Episode, n / N (%)	4/16 (25.0)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	1/8 (12.5)	1/10 (10.0)	NA
>=20, n / N (%)	12/67 (17.9)	9/66 (13.6)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-pf-wors15-tte-201-int.sas:t-sf36-pf-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.3.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

2.3.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

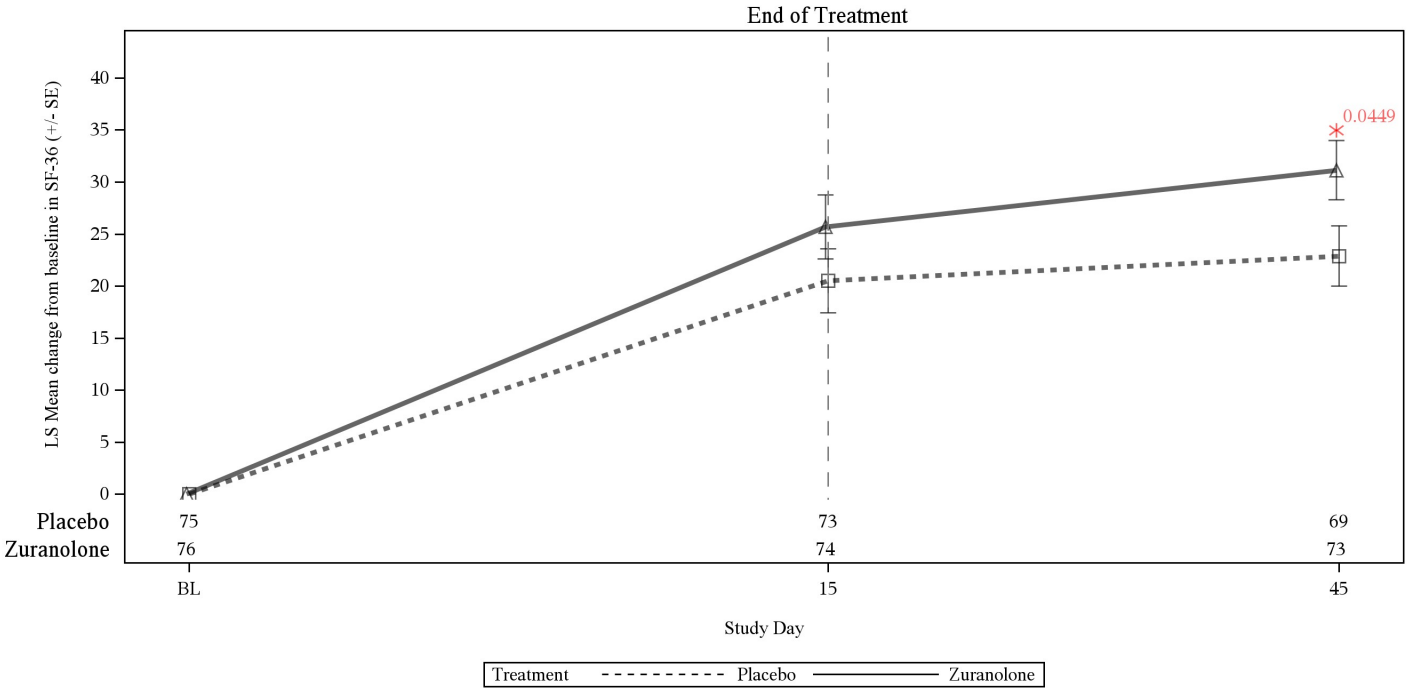
2.4 körperliche Rollenfunktion

2.4.1 MMRM

2.4.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-ovr.sas:f-sf36-rp-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale: 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	20.52 (3.094)	25.70 (3.068)
95% CI for the LS Mean	14.40, 26.63	19.63, 31.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.18 (4.363)
95% CI for the LS Mean		-3.44, 13.81
p-value		0.2369
Hedges' g (Zuranolone vs. Placebo)		0.195
95% CI for Hedges' g		-0.1291, 0.5190
Day 45		
n	69	73
LS Mean (SE)	22.89 (2.911)	31.14 (2.839)
95% CI for the LS Mean	17.14, 28.65	25.52, 36.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.25 (4.074)
95% CI for the LS Mean		0.19, 16.30
p-value		0.0449
Hedges' g (Zuranolone vs. Placebo)		0.338
95% CI for Hedges' g		0.0066, 0.6694

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-ovr.sas:t-sf36-rp-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.4.1.2 Subgruppen

2.4.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.9093
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.3107
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.4091
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.5058
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-int.sas:t-sf36-rp-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.3981(a)
25-29.9	20	21	0.1893(b)
>=30	34	42	0.6761(c)
Onset of PPD			
3rd Trimester	32	32	0.8175
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.4640
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.9660
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-int.sas:t-sf36-rp-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

2.4.1.2 .2 Subgruppenanalysen

2.4.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	22.05 (3.988)	30.26 (4.844)
95% CI for the LS Mean	13.98, 30.11	20.46, 40.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.22 (6.384)
95% CI for the LS Mean		-4.69, 21.13
p-value		0.2055
Hedges' g (Zuranolone vs. Placebo)		0.397
95% CI for Hedges' g		-0.2249, 1.0190
Day 45		
n	25	16
LS Mean (SE)	22.80 (4.614)	31.62 (5.792)
95% CI for the LS Mean	13.46, 32.13	19.92, 43.32
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.82 (7.519)
95% CI for the LS Mean		-6.36, 24.00
p-value		0.2473
Hedges' g (Zuranolone vs. Placebo)		0.368
95% CI for Hedges' g		-0.2641, 1.0009

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Age Group: 217-PPD-201B - ITT population

Page: 2 of 2

Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	19.52 (4.167)	24.44 (3.818)
95% CI for the LS Mean	11.25, 27.79	16.87, 32.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.92 (5.655)
95% CI for the LS Mean		-6.30, 16.14
p-value		0.3863
Hedges' g (Zuranolone vs. Placebo)		0.169
95% CI for Hedges' g		-0.2154, 0.5539
Day 45		
n	44	57
LS Mean (SE)	22.76 (3.768)	31.15 (3.332)
95% CI for the LS Mean	15.28, 30.23	24.53, 37.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.39 (5.035)
95% CI for the LS Mean		-1.60, 18.38
p-value		0.0988
Hedges' g (Zuranolone vs. Placebo)		0.332
95% CI for Hedges' g		-0.0642, 0.7278

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.4.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 2

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	28.54 (5.538)	29.82 (4.864)
95% CI for the LS Mean	17.40, 39.68	20.03, 39.60
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.28 (7.457)
95% CI for the LS Mean		-13.72, 16.27
p-value		0.8647
Hedges' g (Zuranolone vs. Placebo)		0.048
95% CI for Hedges' g		-0.5104, 0.6065
Day 45		
n	22	28
LS Mean (SE)	31.67 (4.718)	35.35 (4.167)
95% CI for the LS Mean	22.18, 41.15	26.98, 43.73
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.69 (6.423)
95% CI for the LS Mean		-9.22, 16.59
p-value		0.5688
Hedges' g (Zuranolone vs. Placebo)		0.161
95% CI for Hedges' g		-0.3984, 0.7202

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	16.45 (3.726)	23.77 (3.925)
95% CI for the LS Mean	9.05, 23.85	15.97, 31.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.32 (5.415)
95% CI for the LS Mean		-3.44, 18.07
p-value		0.1799
Hedges' g (Zuranolone vs. Placebo)		0.273
95% CI for Hedges' g		-0.1278, 0.6730
Day 45		
n	47	45
LS Mean (SE)	18.23 (3.680)	29.30 (3.778)
95% CI for the LS Mean	10.92, 25.54	21.79, 36.80
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.07 (5.281)
95% CI for the LS Mean		0.58, 21.56
p-value		0.0389
Hedges' g (Zuranolone vs. Placebo)		0.433
95% CI for Hedges' g		0.0199, 0.8470

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.4.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	21.63 (5.165)	26.93 (5.165)
95% CI for the LS Mean	11.30, 31.96	16.60, 37.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.30 (7.309)
95% CI for the LS Mean		-9.32, 19.93
p-value		0.4708
Hedges' g (Zuranolone vs. Placebo)		0.182
95% CI for Hedges' g		-0.3168, 0.6809
Day 45		
n	30	30
LS Mean (SE)	22.94 (4.304)	36.94 (4.304)
95% CI for the LS Mean	14.32, 31.55	28.32, 45.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		14.00 (6.092)
95% CI for the LS Mean		1.81, 26.20
p-value		0.0252
Hedges' g (Zuranolone vs. Placebo)		0.586
95% CI for Hedges' g		0.0690, 1.1026

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	20.98 (3.966)	23.71 (3.805)
95% CI for the LS Mean	13.08, 28.88	16.13, 31.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.73 (5.540)
95% CI for the LS Mean		-8.30, 13.77
p-value		0.6232
Hedges' g (Zuranolone vs. Placebo)		0.109
95% CI for Hedges' g		-0.3275, 0.5448
Day 45		
n	36	42
LS Mean (SE)	23.36 (4.100)	25.43 (3.827)
95% CI for the LS Mean	15.19, 31.53	17.81, 33.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.07 (5.651)
95% CI for the LS Mean		-9.18, 13.33
p-value		0.7148
Hedges' g (Zuranolone vs. Placebo)		0.082
95% CI for Hedges' g		-0.3629, 0.5279

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.4.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	22.88 (7.869)	29.23 (7.309)
95% CI for the LS Mean	6.69, 39.07	14.19, 44.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.35 (10.750)
95% CI for the LS Mean		-15.77, 28.47
p-value		0.5601
Hedges' g (Zuranolone vs. Placebo)		0.217
95% CI for Hedges' g		-0.5277, 0.9621
Day 45		
n	11	15
LS Mean (SE)	28.69 (7.184)	45.48 (6.252)
95% CI for the LS Mean	13.89, 43.48	32.57, 58.39
Difference (Zuranolone - Placebo)		
LS Mean (SE)		16.79 (9.527)
95% CI for the LS Mean		-2.85, 36.43
p-value		0.0904
Hedges' g (Zuranolone vs. Placebo)		0.678
95% CI for Hedges' g		-0.1219, 1.4772

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 2 of 2

Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	19.92 (3.371)	25.00 (3.393)
95% CI for the LS Mean	13.24, 26.60	18.28, 31.72
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.08 (4.789)
95% CI for the LS Mean		-4.40, 14.57
p-value		0.2910
Hedges' g (Zuranolone vs. Placebo)		0.193
95% CI for Hedges' g		-0.1669, 0.5534
Day 45		
n	58	58
LS Mean (SE)	21.56 (3.188)	27.62 (3.190)
95% CI for the LS Mean	15.25, 27.88	21.30, 33.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.06 (4.519)
95% CI for the LS Mean		-2.89, 15.01
p-value		0.1827
Hedges' g (Zuranolone vs. Placebo)		0.247
95% CI for Hedges' g		-0.1181, 0.6126

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.4.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	17.73 (3.484)	29.31 (4.358)
95% CI for the LS Mean	10.60, 24.85	20.40, 38.22
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.58 (5.621)
95% CI for the LS Mean		0.09, 23.08
p-value		0.0484
Hedges' g (Zuranolone vs. Placebo)		0.716
95% CI for Hedges' g		-0.0031, 1.4355
Day 45		
n	18	12
LS Mean (SE)	7.98 (5.667)	27.30 (6.987)
95% CI for the LS Mean	-3.59, 19.56	13.02, 41.58
Difference (Zuranolone - Placebo)		
LS Mean (SE)		19.32 (9.023)
95% CI for the LS Mean		0.89, 37.75
p-value		0.0406
Hedges' g (Zuranolone vs. Placebo)		0.776
95% CI for Hedges' g		0.0199, 1.5327

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population
Page: 2 of 3
BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	19.77 (7.376)	25.40 (7.338)
95% CI for the LS Mean	4.80, 34.74	10.52, 40.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.63 (10.434)
95% CI for the LS Mean		-15.54, 26.81
p-value		0.5925
Hedges' g (Zuranolone vs. Placebo)		0.167
95% CI for Hedges' g		-0.4535, 0.7883
Day 45		
n	20	20
LS Mean (SE)	26.96 (6.486)	30.97 (6.458)
95% CI for the LS Mean	13.80, 40.12	17.87, 44.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.01 (9.188)
95% CI for the LS Mean		-14.63, 22.65
p-value		0.6651
Hedges' g (Zuranolone vs. Placebo)		0.135
95% CI for Hedges' g		-0.4852, 0.7558

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	22.08 (4.649)	24.96 (4.167)
95% CI for the LS Mean	12.81, 31.35	16.65, 33.26
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.87 (6.262)
95% CI for the LS Mean		-9.61, 15.36
p-value		0.6476
Hedges' g (Zuranolone vs. Placebo)		0.106
95% CI for Hedges' g		-0.3525, 0.5649
Day 45		
n	31	41
LS Mean (SE)	28.37 (3.635)	32.58 (3.169)
95% CI for the LS Mean	21.12, 35.62	26.26, 38.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.20 (4.848)
95% CI for the LS Mean		-5.47, 13.87
p-value		0.3888
Hedges' g (Zuranolone vs. Placebo)		0.204
95% CI for Hedges' g		-0.2635, 0.6719

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.4.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	20.95 (4.852)	26.38 (4.771)
95% CI for the LS Mean	11.24, 30.66	16.83, 35.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.43 (6.831)
95% CI for the LS Mean		-8.24, 19.10
p-value		0.4298
Hedges' g (Zuranolone vs. Placebo)		0.198
95% CI for Hedges' g		-0.2973, 0.6930
Day 45		
n	29	30
LS Mean (SE)	25.55 (4.588)	34.33 (4.512)
95% CI for the LS Mean	16.36, 34.75	25.29, 43.37
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.78 (6.470)
95% CI for the LS Mean		-4.19, 21.74
p-value		0.1804
Hedges' g (Zuranolone vs. Placebo)		0.349
95% CI for Hedges' g		-0.1656, 0.8629

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	20.35 (4.145)	24.90 (4.134)
95% CI for the LS Mean	12.10, 28.60	16.68, 33.13
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.55 (5.862)
95% CI for the LS Mean		-7.11, 16.22
p-value		0.4396
Hedges' g (Zuranolone vs. Placebo)		0.168
95% CI for Hedges' g		-0.2605, 0.5964
Day 45		
n	40	43
LS Mean (SE)	21.23 (3.736)	28.80 (3.624)
95% CI for the LS Mean	13.80, 28.66	21.59, 36.01
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.57 (5.214)
95% CI for the LS Mean		-2.80, 17.95
p-value		0.1502
Hedges' g (Zuranolone vs. Placebo)		0.316
95% CI for Hedges' g		-0.1171, 0.7493

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.4.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	24.55 (7.287)	19.93 (7.309)
95% CI for the LS Mean	9.20, 39.91	4.52, 35.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.63 (10.653)
95% CI for the LS Mean		-27.04, 17.79
p-value		0.6694
Hedges' g (Zuranolone vs. Placebo)		-0.186
95% CI for Hedges' g		-1.0644, 0.6924
Day 45		
n	9	10
LS Mean (SE)	26.79 (7.145)	28.68 (6.810)
95% CI for the LS Mean	11.76, 41.83	14.27, 43.08
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.88 (10.275)
95% CI for the LS Mean		-19.74, 23.50
p-value		0.8567
Hedges' g (Zuranolone vs. Placebo)		0.080
95% CI for Hedges' g		-0.8205, 0.9813

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	19.99 (3.424)	26.48 (3.391)
95% CI for the LS Mean	13.21, 26.77	19.77, 33.19
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.49 (4.824)
95% CI for the LS Mean		-3.06, 16.04
p-value		0.1810
Hedges' g (Zuranolone vs. Placebo)		0.237
95% CI for Hedges' g		-0.1117, 0.5864
Day 45		
n	60	63
LS Mean (SE)	22.42 (3.219)	31.39 (3.148)
95% CI for the LS Mean	16.05, 28.80	25.16, 37.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.97 (4.509)
95% CI for the LS Mean		0.05, 17.90
p-value		0.0489
Hedges' g (Zuranolone vs. Placebo)		0.357
95% CI for Hedges' g		0.0004, 0.7131

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.4.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	22.45 (3.317)	27.45 (3.179)
95% CI for the LS Mean	15.88, 29.02	21.15, 33.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.00 (4.601)
95% CI for the LS Mean		-4.12, 14.11
p-value		0.2798
Hedges' g (Zuranolone vs. Placebo)		0.195
95% CI for Hedges' g		-0.1598, 0.5493
Day 45		
n	55	64
LS Mean (SE)	23.66 (3.344)	31.95 (3.113)
95% CI for the LS Mean	17.04, 30.29	25.79, 38.12
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.29 (4.574)
95% CI for the LS Mean		-0.77, 17.35
p-value		0.0725
Hedges' g (Zuranolone vs. Placebo)		0.331
95% CI for Hedges' g		-0.0317, 0.6939

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-rp-mmrm-201-by.sas:t-sf36-rp-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	10.42 (8.745)	17.46 (10.381)
95% CI for the LS Mean	-7.75, 28.58	-4.10, 39.01
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.04 (13.742)
95% CI for the LS Mean		-21.47, 35.55
p-value		0.6136
Hedges' g (Zuranolone vs. Placebo)		0.205
95% CI for Hedges' g		-0.6088, 1.0184
Day 45		
n	14	9
LS Mean (SE)	17.56 (6.158)	28.99 (7.604)
95% CI for the LS Mean	4.71, 30.42	13.18, 44.81
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.43 (10.052)
95% CI for the LS Mean		-9.49, 32.36
p-value		0.2684
Hedges' g (Zuranolone vs. Placebo)		0.468
95% CI for Hedges' g		-0.3798, 1.3167

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

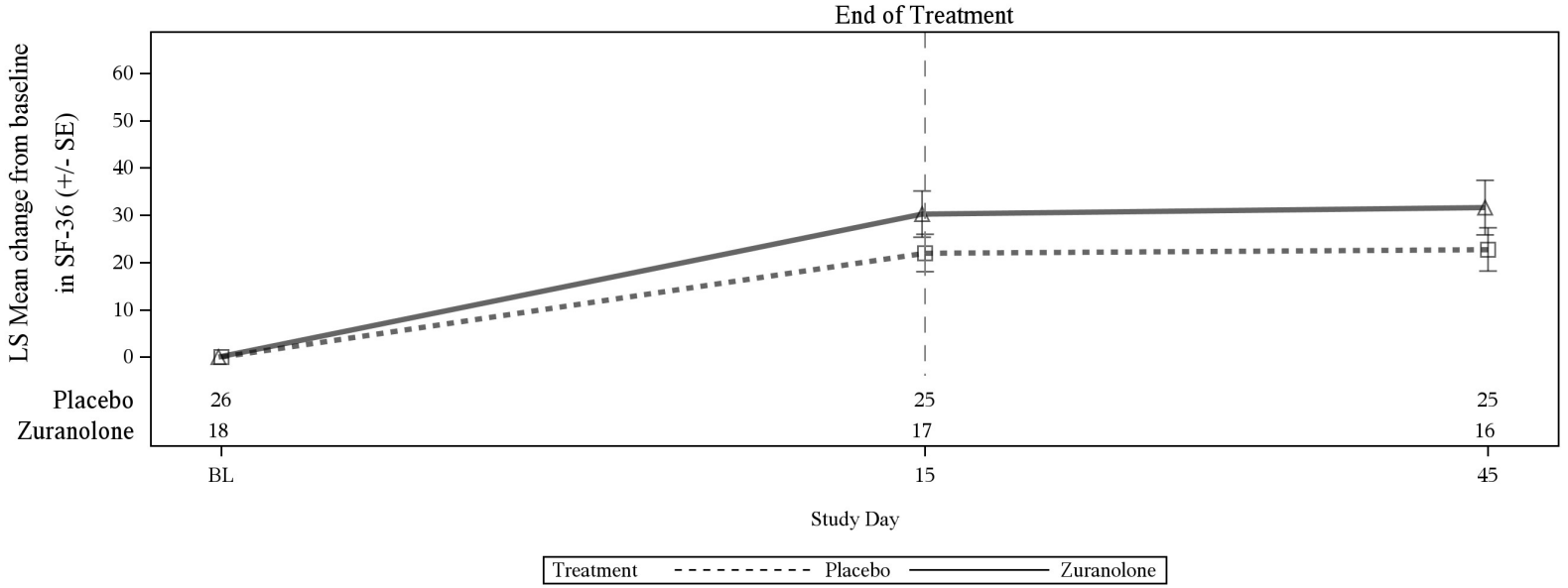
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2.4.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

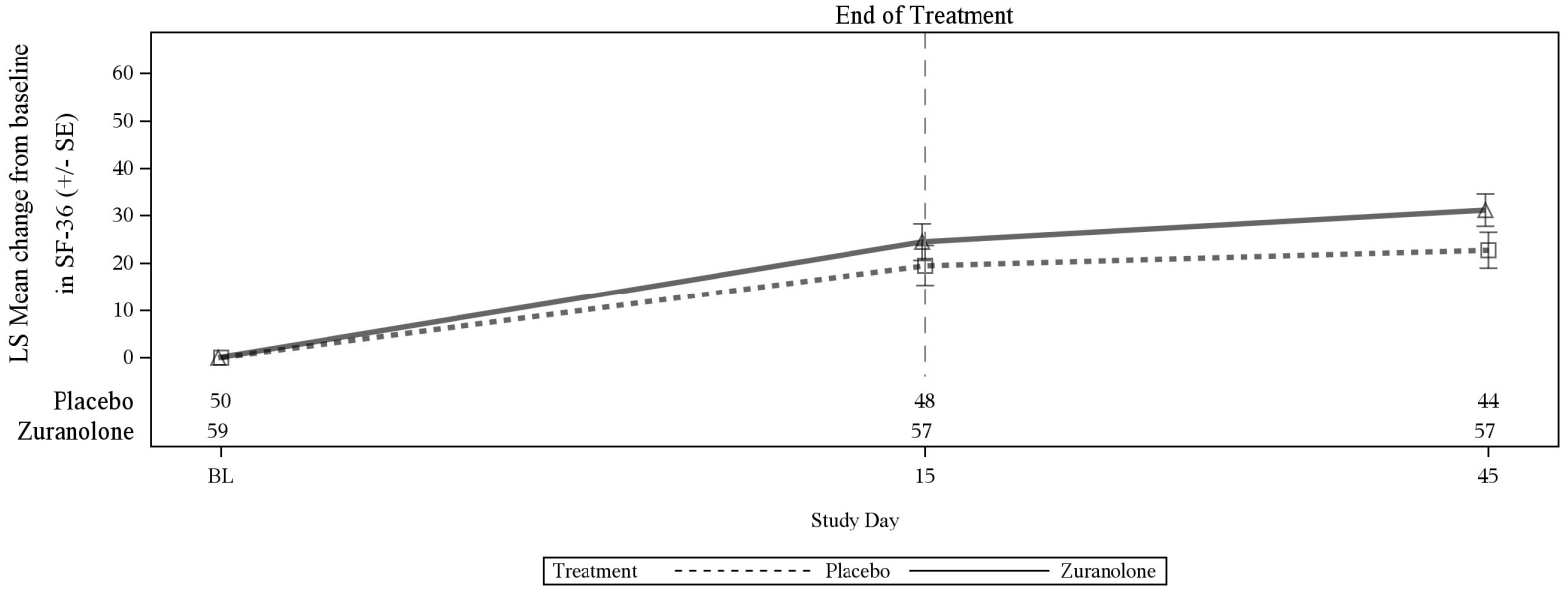
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Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

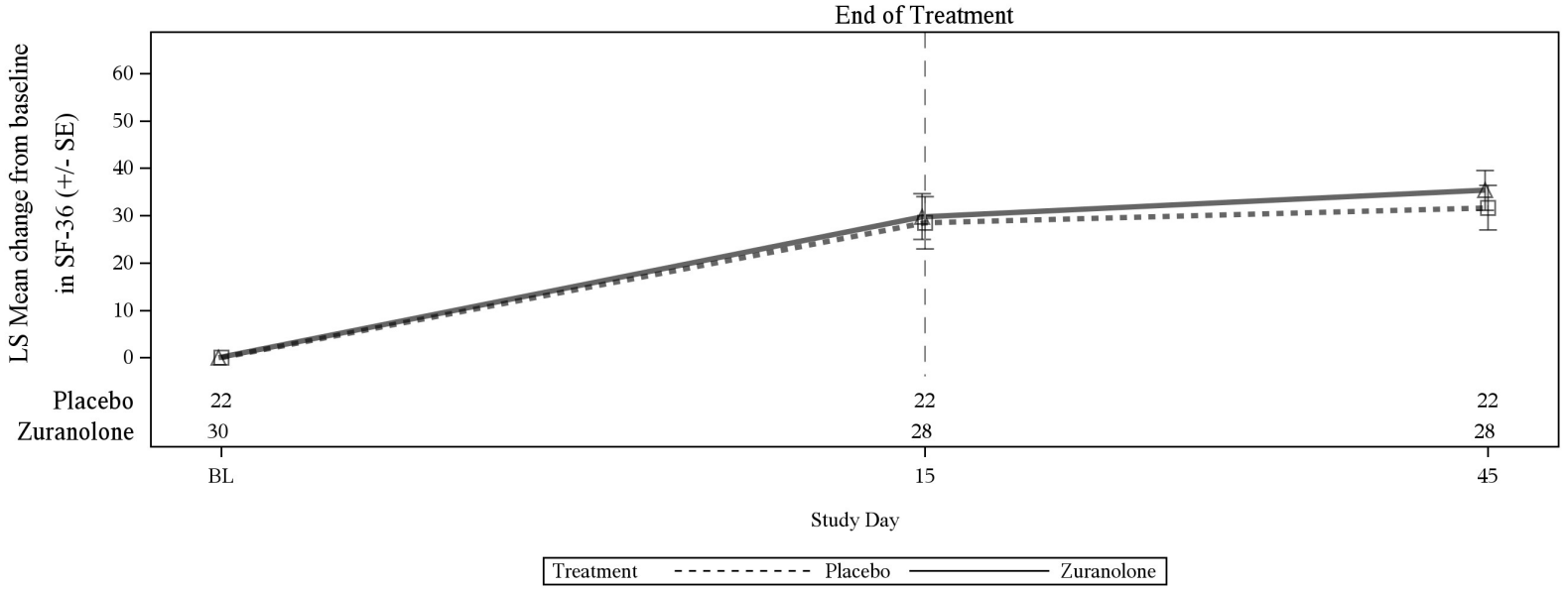
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

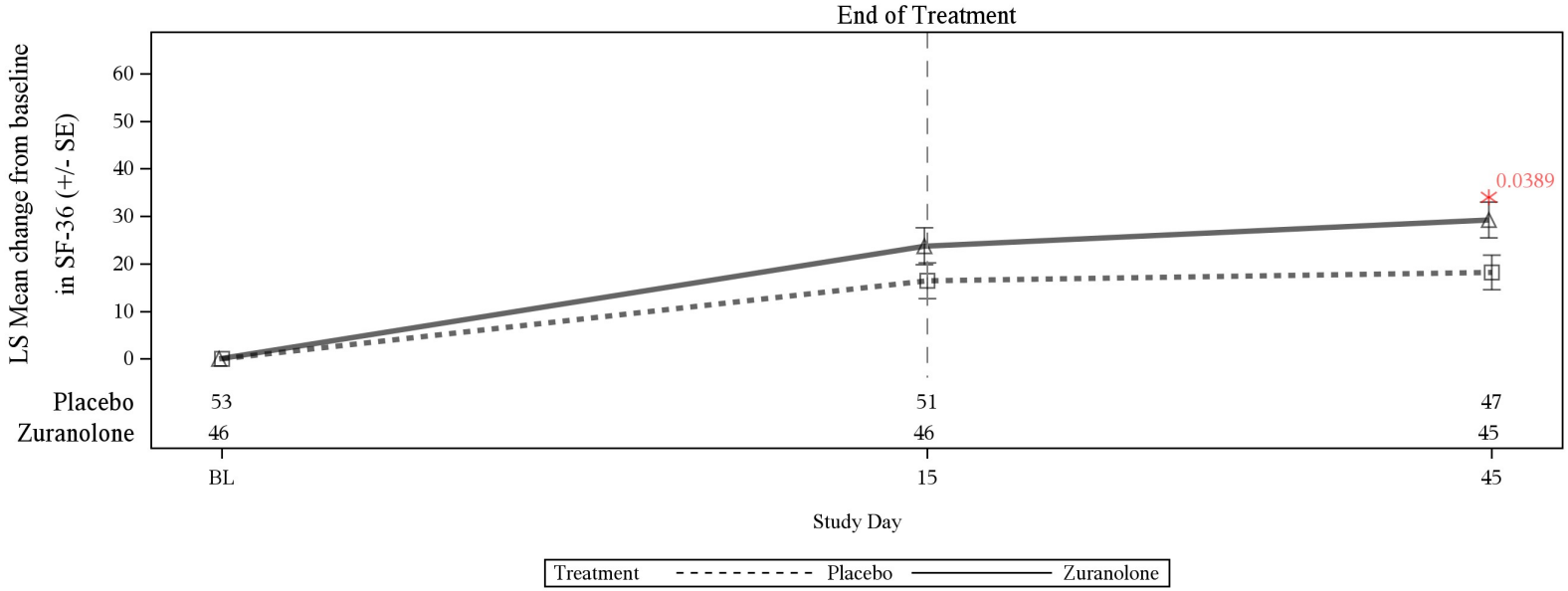
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Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

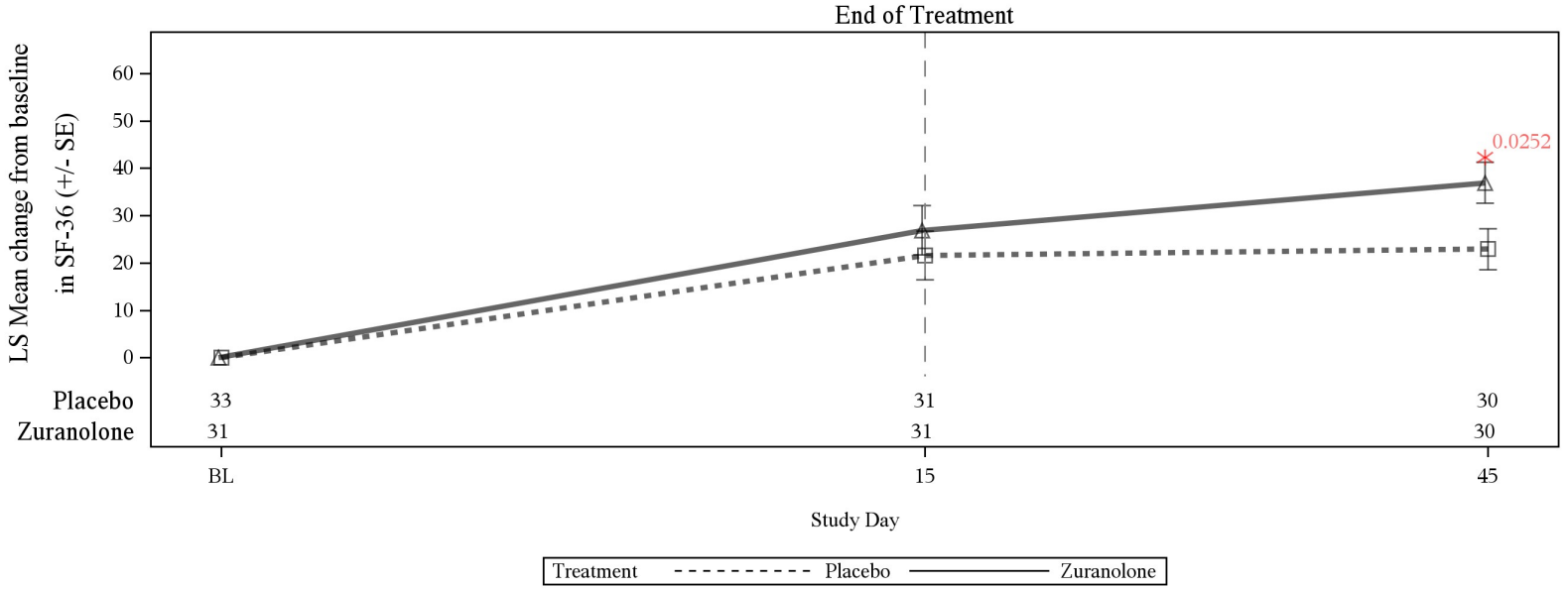
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

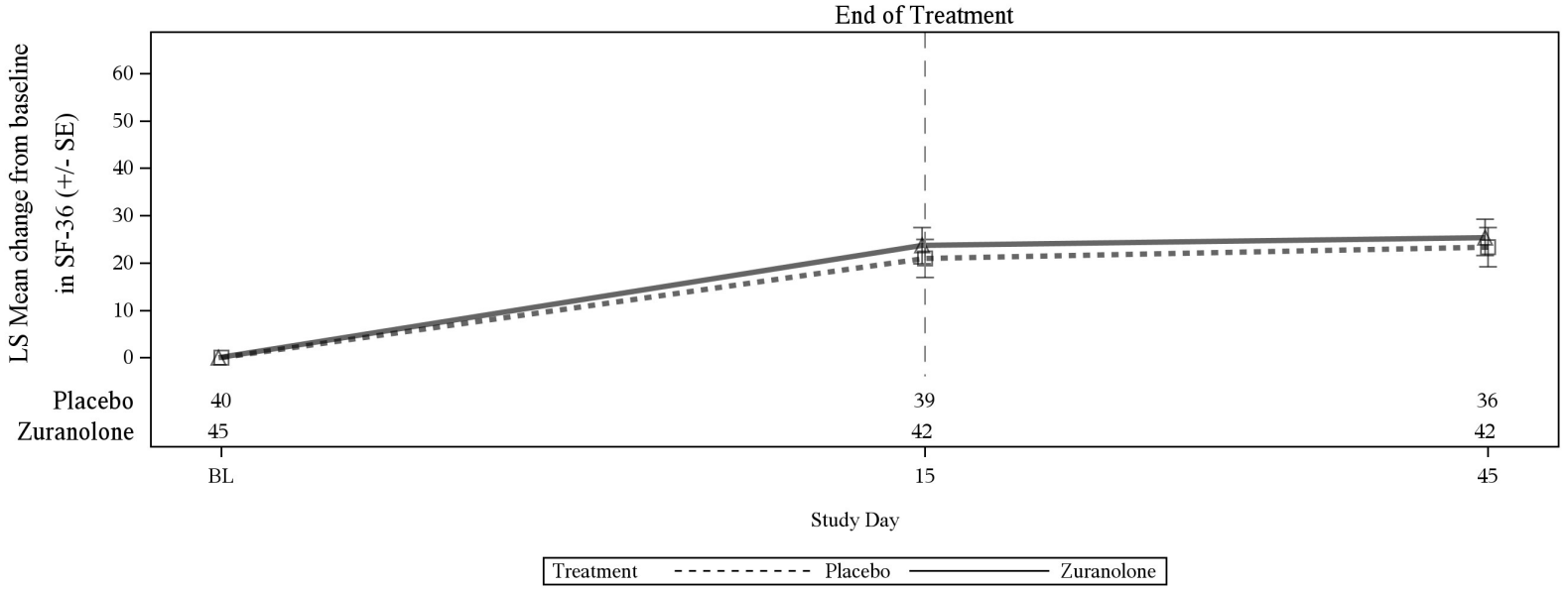
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

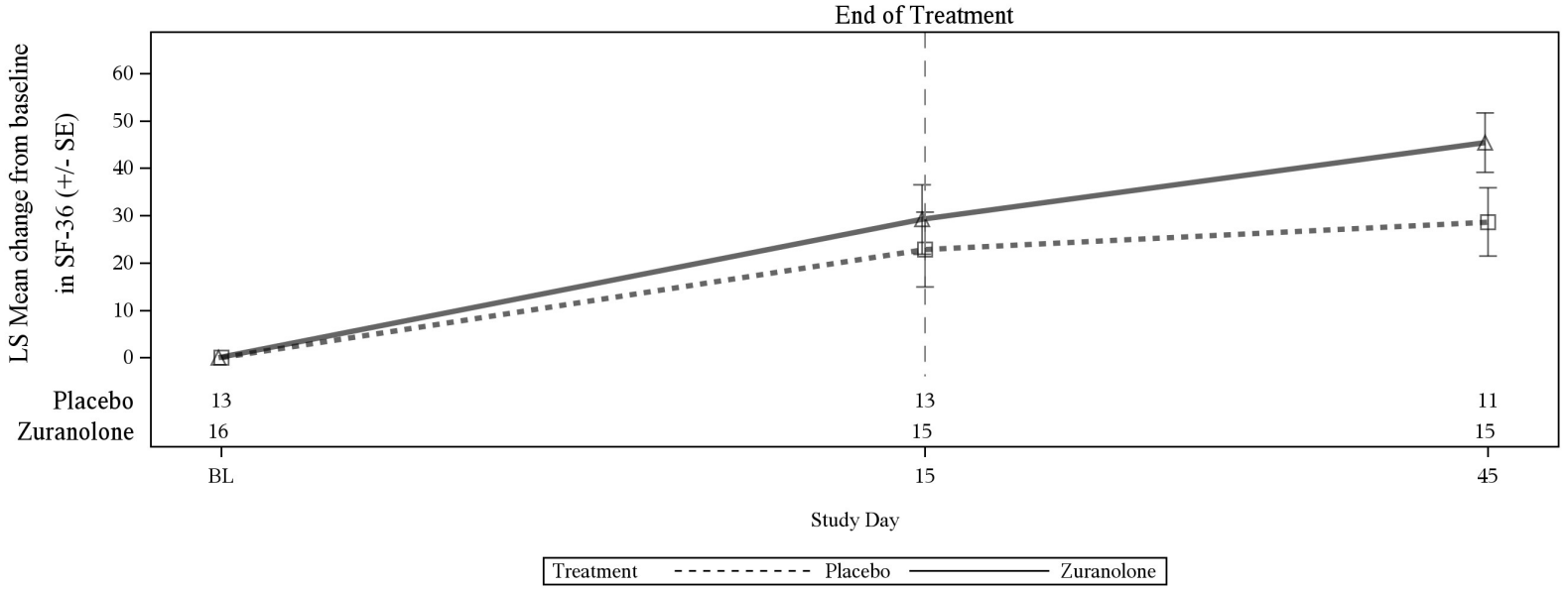
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 7 of 17

Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

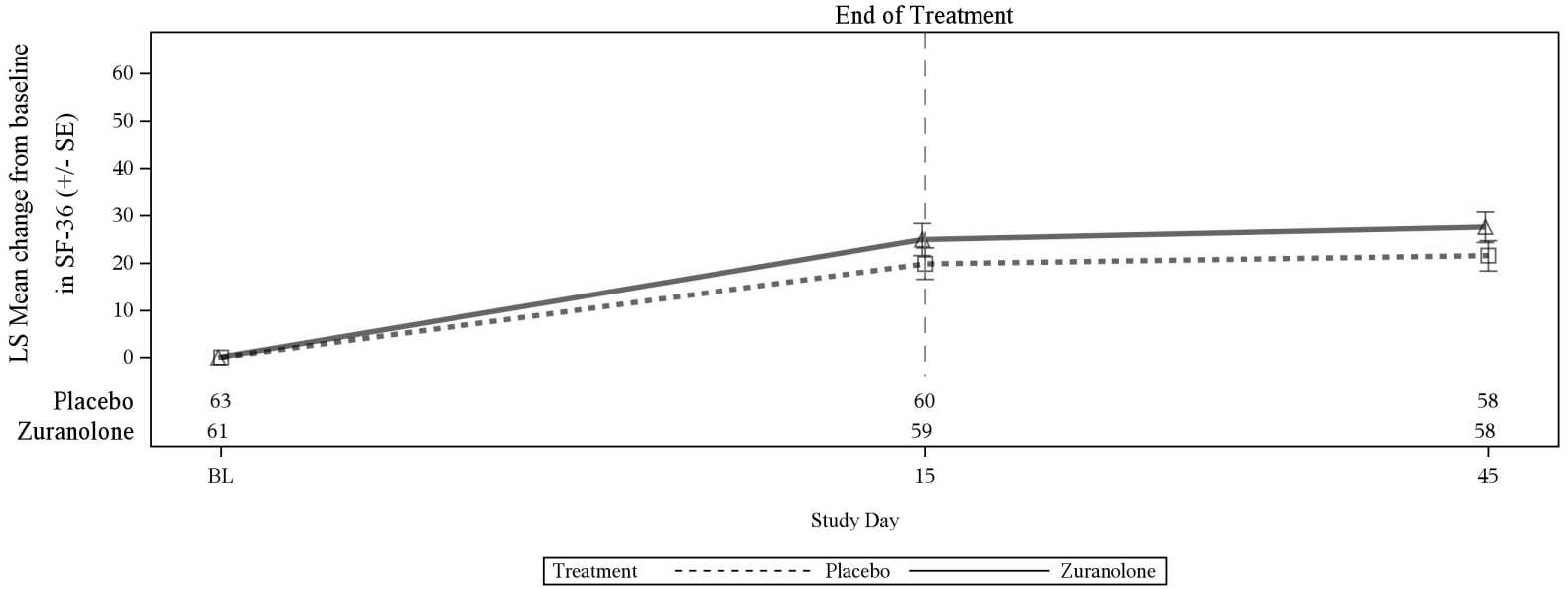
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Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

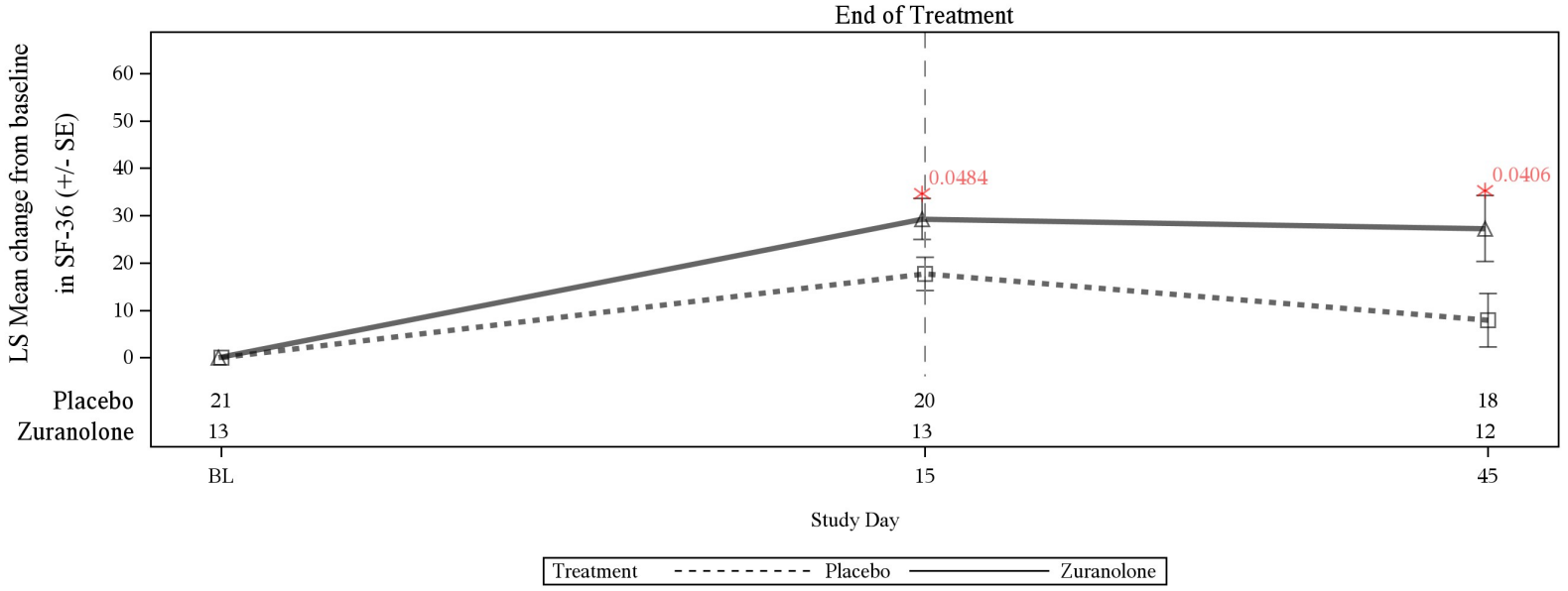
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

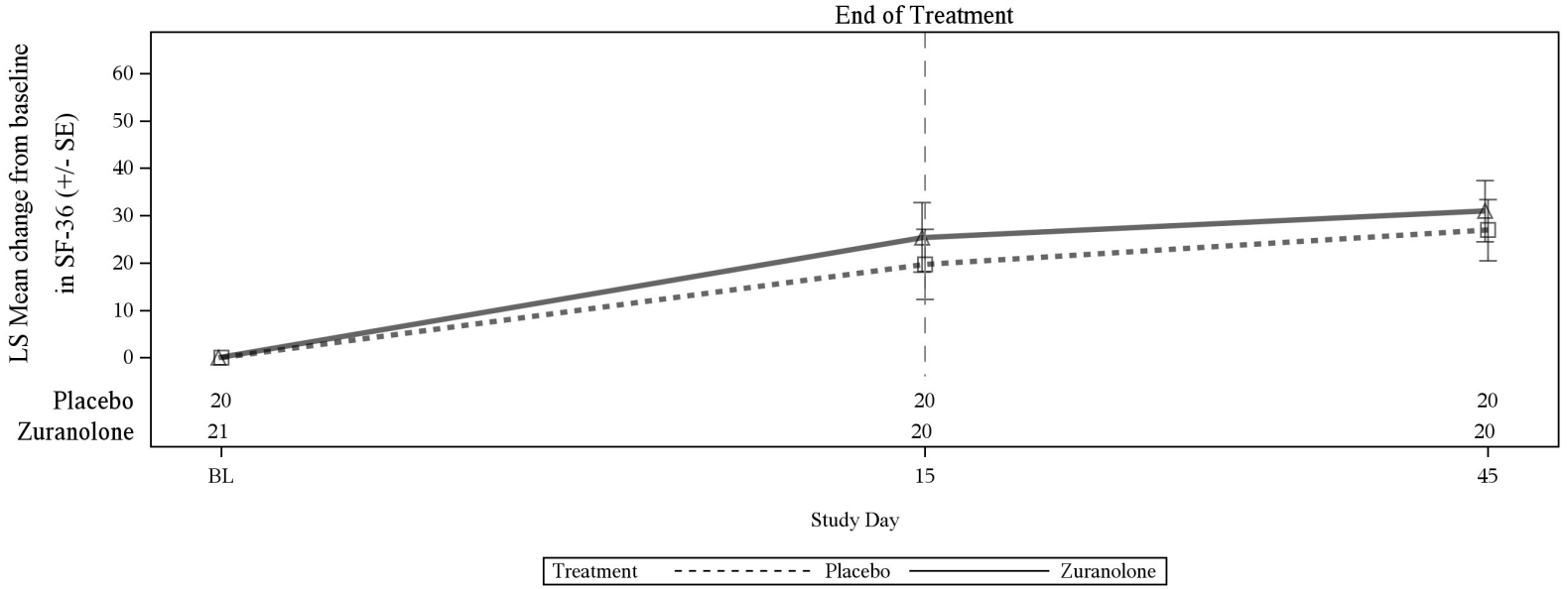
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

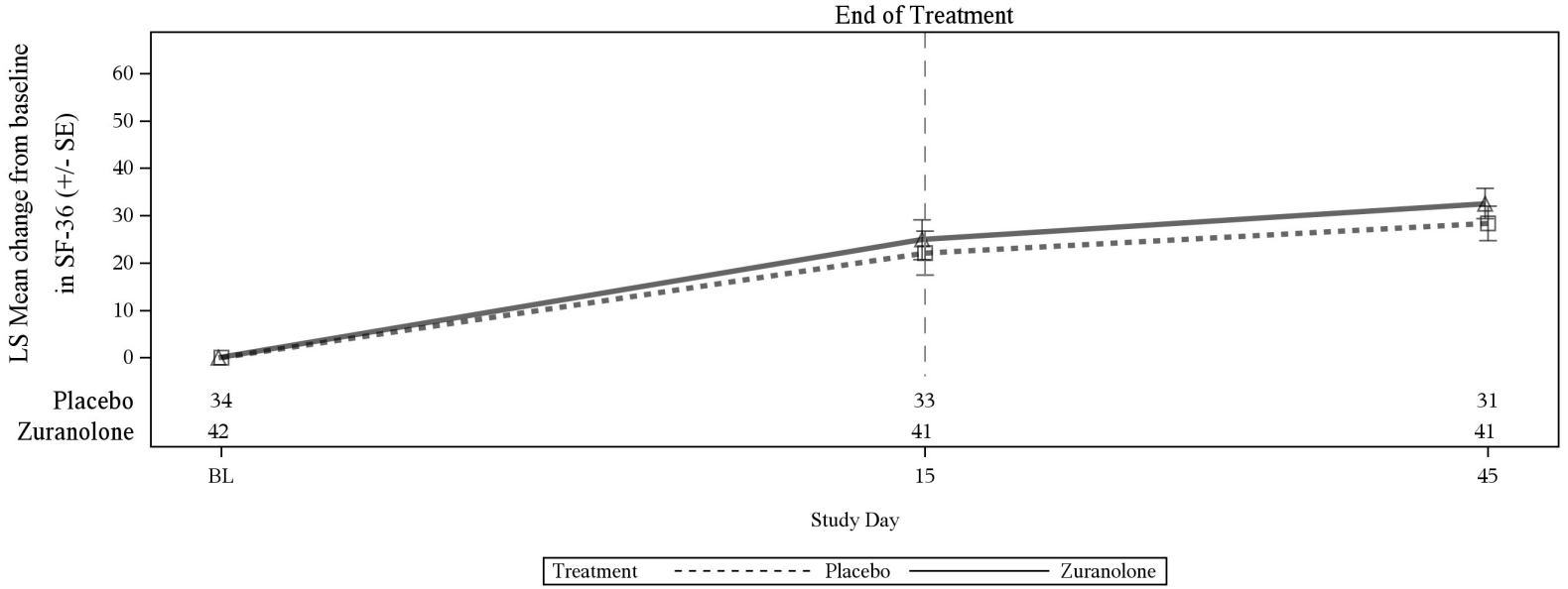
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

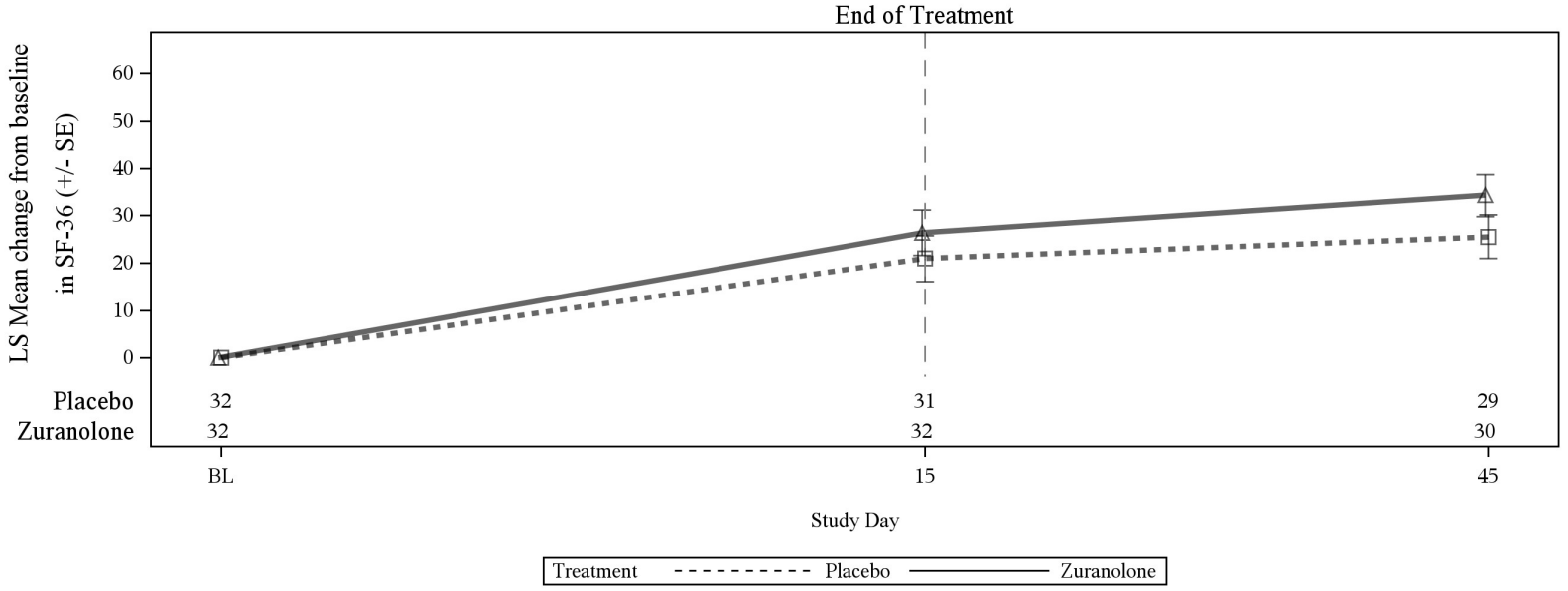
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

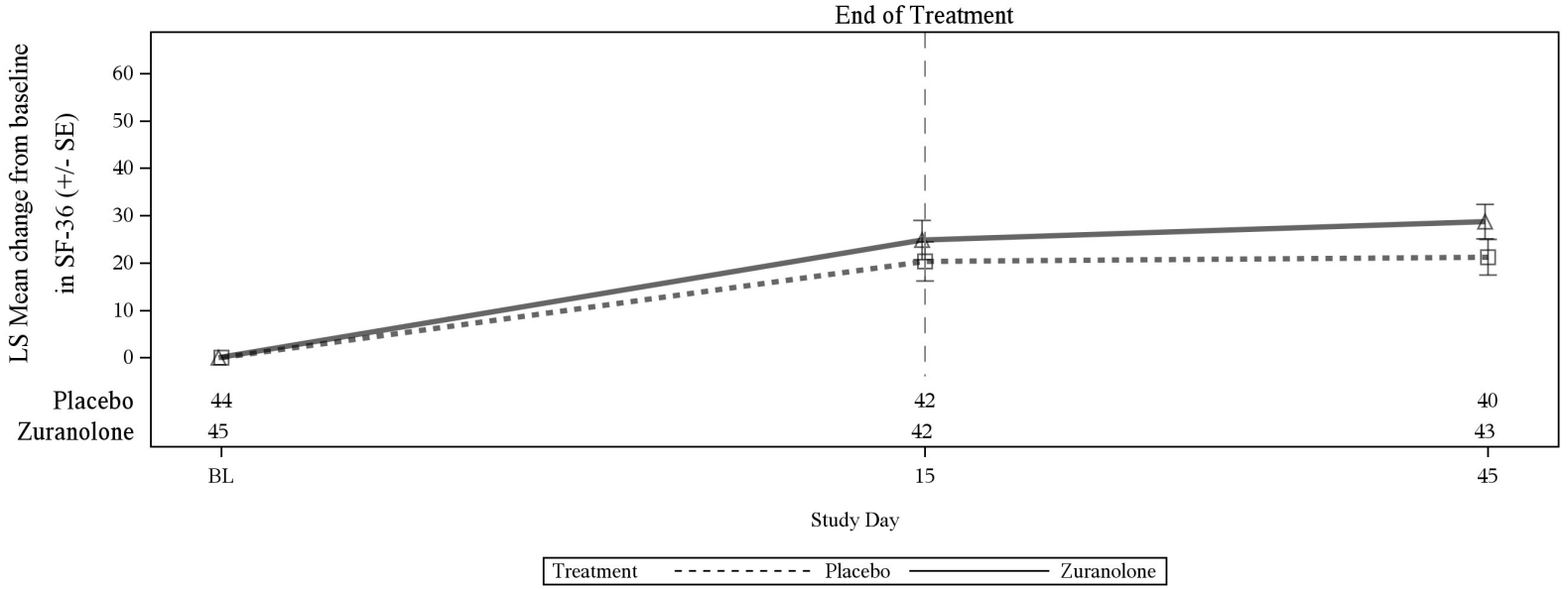
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

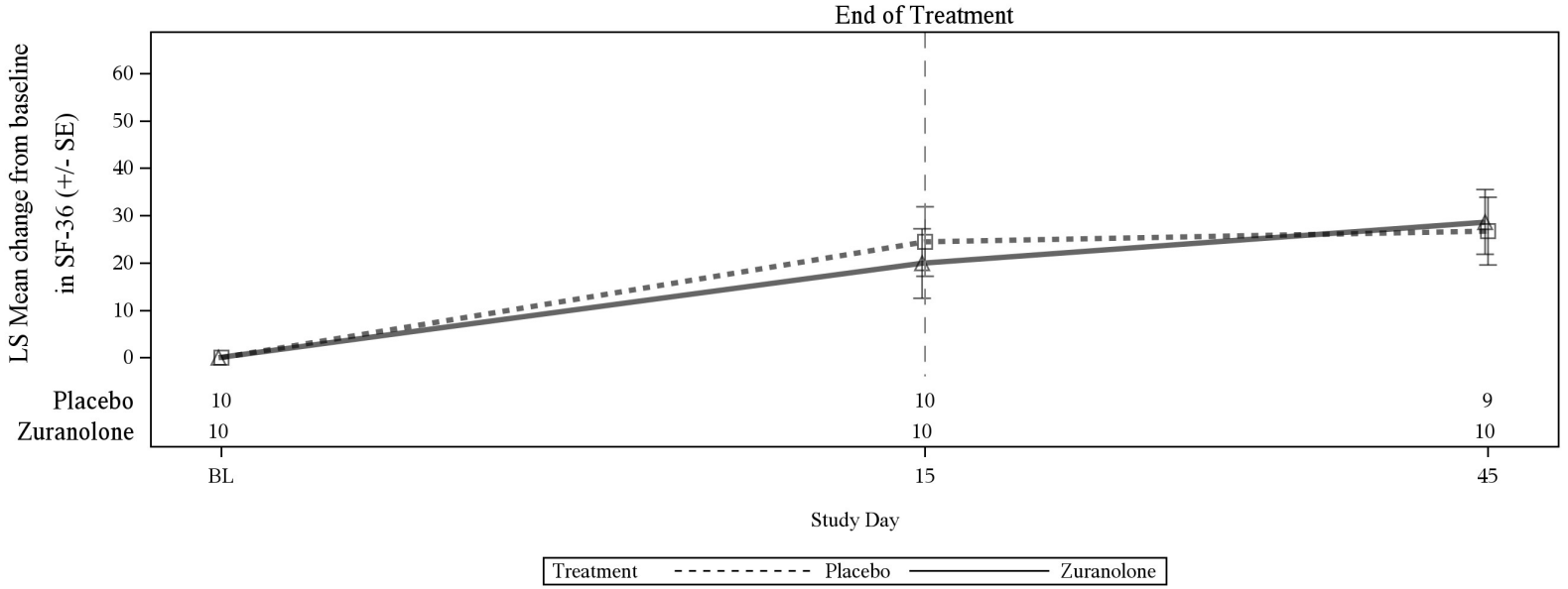
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

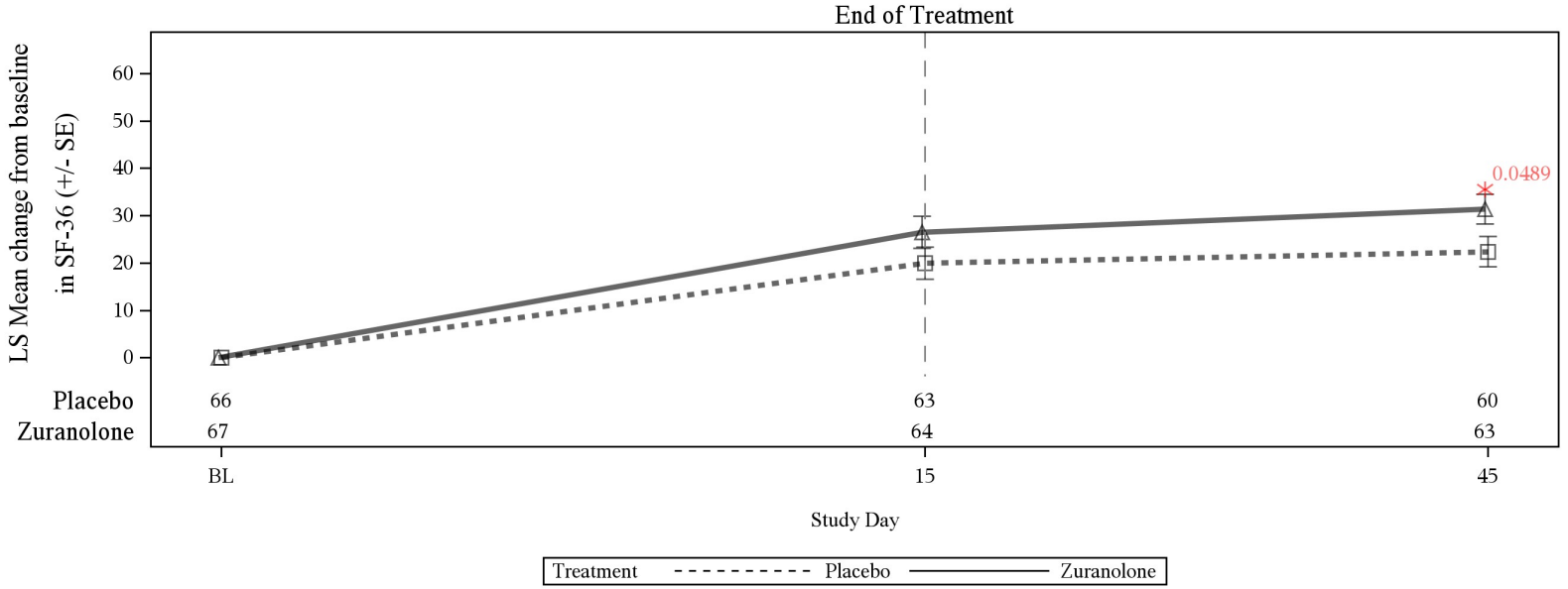
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

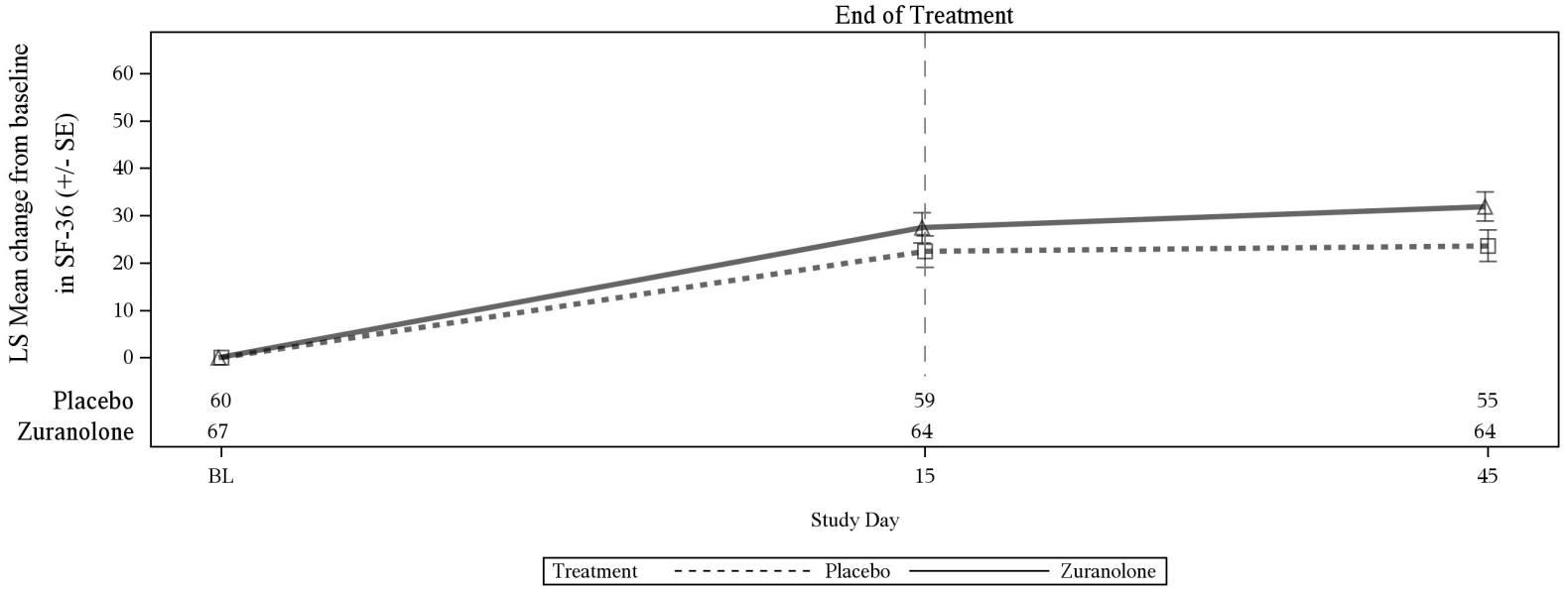
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

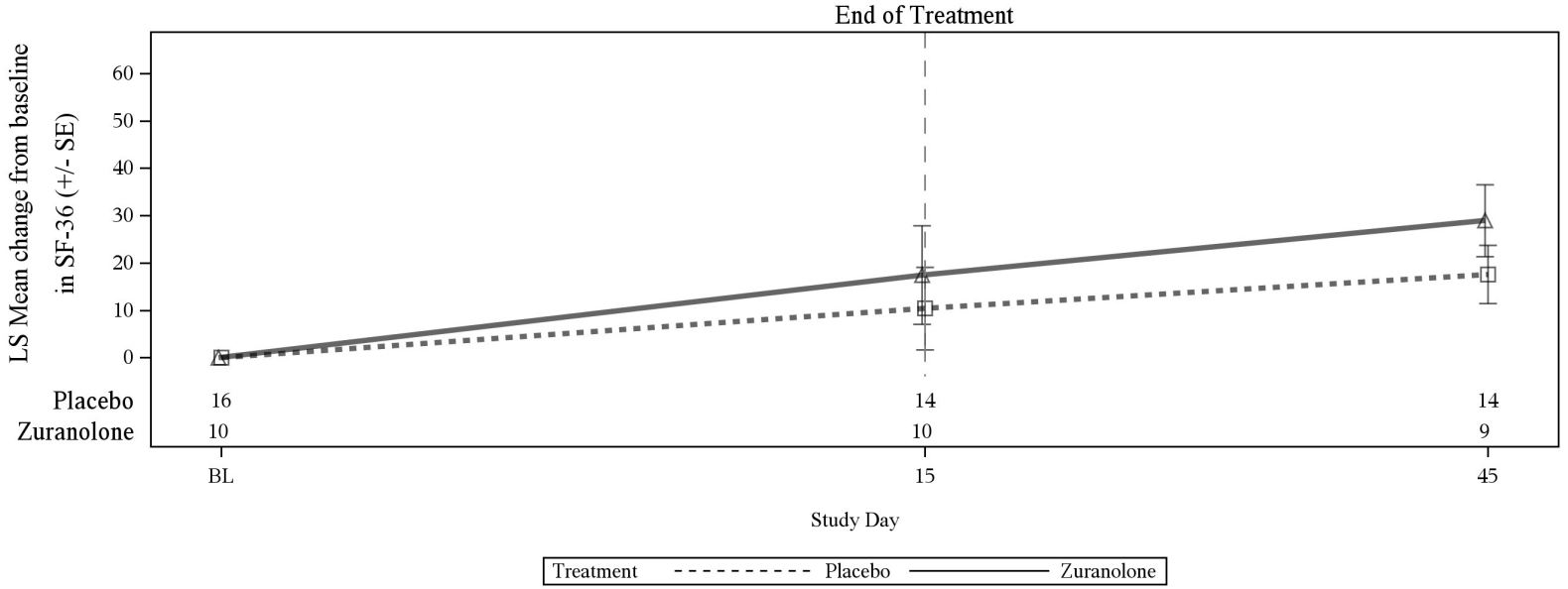
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Physical Subscale by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-rp-mmrm-201-by.sas:f-sf36-rp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

2.4.2 Ansprechen

2.4.2.1 Responder-Analysen

2.4.2.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with a response, n (%) [2]	36 (48.0)	47 (61.8)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.181
95% CI for the RR		(0.893, 1.563)
p-value for RR		0.2425
OR - Odds Ratio (Zuranolone vs. Placebo)		1.626
95% CI for the OR		(0.758, 3.485)
p-value for OR		0.2116
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.
[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-ovr.sas:t-sf36-rp-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	38 (50.7)	50 (65.8)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.191
95% CI for the RR		(0.933, 1.520)
p-value for RR		0.1609
OR - Odds Ratio (Zuranolone vs. Placebo)		1.761
95% CI for the OR		(0.881, 3.517)
p-value for OR		0.1091
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-ovr.sas:t-sf36-rp-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.4.2.1 .2 Subgruppen

2.4.2.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	36 (48.0)	47 (61.8)	
Number of subjects with response at Day 45, n (%)	38 (50.7)	50 (65.8)	
Age Group (years)			0.6728
Day 15			
18 - 24, n / N (%)	11/25 (44.0)	13/17 (76.5)	
25 - 45, n / N (%)	25/50 (50.0)	34/59 (57.6)	
Day 45			
18 - 24, n / N (%)	14/25 (56.0)	14/17 (82.4)	
25 - 45, n / N (%)	24/50 (48.0)	36/59 (61.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-int.sas:t-sf36-rp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.1774
Day 15			
<28, n / N (%)	11/22 (50.0)	19/30 (63.3)	
>=28, n / N (%)	25/53 (47.2)	28/46 (60.9)	
Day 45			
<28, n / N (%)	12/22 (54.5)	20/30 (66.7)	
>=28, n / N (%)	26/53 (49.1)	30/46 (65.2)	
Race Group (Black or African American, White)			0.2474
Day 15			
Black or African American, n / N (%)	16/32 (50.0)	19/31 (61.3)	
White, n / N (%)	19/40 (47.5)	27/44 (61.4)	
Day 45			
Black or African American, n / N (%)	17/32 (53.1)	24/31 (77.4)	
White, n / N (%)	18/40 (45.0)	25/44 (56.8)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-int.sas:t-sf36-rp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.7307
Day 15			
Yes, n / N (%)	6/13 (46.2)	10/16 (62.5)	
No, n / N (%)	30/62 (48.4)	37/60 (61.7)	
Day 45			
Yes, n / N (%)	7/13 (53.8)	13/16 (81.3)	
No, n / N (%)	31/62 (50.0)	37/60 (61.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-int.sas:t-sf36-rp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.0978(a) 0.2481(b) 0.4344(c)
Day 15			
<=24.9, n / N (%)	10/21 (47.6)	8/13 (61.5)	
25-29.9, n / N (%)	10/20 (50.0)	13/21 (61.9)	
>=30, n / N (%)	16/34 (47.1)	26/42 (61.9)	
Day 45			
<=24.9, n / N (%)	8/21 (38.1)	7/13 (53.8)	
25-29.9, n / N (%)	13/20 (65.0)	13/21 (61.9)	
>=30, n / N (%)	17/34 (50.0)	30/42 (71.4)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-int.sas:t-sf36-rp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.2229
Day 15			
3rd Trimester, n / N (%)	14/32 (43.8)	21/32 (65.6)	
Postpartum, n / N (%)	22/43 (51.2)	26/44 (59.1)	
Day 45			
3rd Trimester, n / N (%)	15/32 (46.9)	24/32 (75.0)	
Postpartum, n / N (%)	23/43 (53.5)	26/44 (59.1)	
Family History of PPD			0.2527
Day 15			
Yes, n / N (%)	7/10 (70.0)	7/10 (70.0)	
No/Unknown, n / N (%)	29/65 (44.6)	40/66 (60.6)	
Day 45			
Yes, n / N (%)	6/10 (60.0)	6/10 (60.0)	
No/Unknown, n / N (%)	32/65 (49.2)	44/66 (66.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-int.sas:t-sf36-rp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.2821
Day 15			
1st Episode, n / N (%)	30/59 (50.8)	41/66 (62.1)	
Recurrent Episode, n / N (%)	6/16 (37.5)	6/10 (60.0)	
Day 45			
1st Episode, n / N (%)	32/59 (54.2)	44/66 (66.7)	
Recurrent Episode, n / N (%)	6/16 (37.5)	6/10 (60.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	5/8 (62.5)	5/10 (50.0)	
>=20, n / N (%)	31/67 (46.3)	42/66 (63.6)	
Day 45			
<20, n / N (%)	4/8 (50.0)	6/10 (60.0)	
>=20, n / N (%)	34/67 (50.7)	44/66 (66.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-int.sas:t-sf36-rp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

2.4.2.1 .2 .2 Subgruppenanalysen

2.4.2.1 .2 .2 .1 Alter

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 15		
Number of subjects with a response, n (%) [2]	11 (44.0)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.424
95% CI for the RR		(0.865, 2.343)
p-value for RR		0.1642
Day 45		
Number of subjects with a response, n (%) [2]	14 (56.0)	14 (82.4)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.205
95% CI for the RR		(0.844, 1.719)
p-value for RR		0.3043

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 15		
Number of subjects with a response, n (%) [2]	25 (50.0)	34 (57.6)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.115
95% CI for the RR		(0.797, 1.560)
p-value for RR		0.5245
Day 45		
Number of subjects with a response, n (%) [2]	24 (48.0)	36 (61.0)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.230
95% CI for the RR		(0.895, 1.691)
p-value for RR		0.2026

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.4.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 15		
Number of subjects with a response, n (%) [2]	11 (50.0)	19 (63.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.948
95% CI for the RR		(0.623, 1.442)
p-value for RR		0.8031
Day 45		
Number of subjects with a response, n (%) [2]	12 (54.5)	20 (66.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.915
95% CI for the RR		(0.611, 1.369)
p-value for RR		0.6650

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 15		
Number of subjects with a response, n (%) [2]	25 (47.2)	28 (60.9)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.315
95% CI for the RR		(0.921, 1.877)
p-value for RR		0.1323
Day 45		
Number of subjects with a response, n (%) [2]	26 (49.1)	30 (65.2)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.354
95% CI for the RR		(0.996, 1.841)
p-value for RR		0.0528

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.4.2.1 .2 .2 .3 Abstammung

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 15		
Number of subjects with a response, n (%) [2]	16 (50.0)	19 (61.3)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.264
95% CI for the RR		(0.827, 1.934)
p-value for RR		0.2796
Day 45		
Number of subjects with a response, n (%) [2]	17 (53.1)	24 (77.4)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.503
95% CI for the RR		(1.066, 2.118)
p-value for RR		0.0200

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 15		
Number of subjects with a response, n (%) [2]	19 (47.5)	27 (61.4)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.000
95% CI for the RR		(0.691, 1.446)
p-value for RR		0.9986
Day 45		
Number of subjects with a response, n (%) [2]	18 (45.0)	25 (56.8)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.977
95% CI for the RR		(0.673, 1.419)
p-value for RR		0.9028

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.4.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 15		
Number of subjects with a response, n (%) [2]	6 (46.2)	10 (62.5)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.286
95% CI for the RR		(0.644, 2.570)
p-value for RR		0.4762
Day 45		
Number of subjects with a response, n (%) [2]	7 (53.8)	13 (81.3)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.433
95% CI for the RR		(0.842, 2.440)
p-value for RR		0.1852

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 15		
Number of subjects with a response, n (%) [2]	30 (48.4)	37 (61.7)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.171
95% CI for the RR		(0.863, 1.588)
p-value for RR		0.3103
Day 45		
Number of subjects with a response, n (%) [2]	31 (50.0)	37 (61.7)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.133
95% CI for the RR		(0.861, 1.492)
p-value for RR		0.3727

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.4.2.1 .2 .2 .5 BMI

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 15		
Number of subjects with a response, n (%) [2]	10 (47.6)	8 (61.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.871
95% CI for the RR		(1.093, 3.201)
p-value for RR		0.0223
Day 45		
Number of subjects with a response, n (%) [2]	8 (38.1)	7 (53.8)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.046
95% CI for the RR		(1.082, 3.871)
p-value for RR		0.0277

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 15		
Number of subjects with a response, n (%) [2]	10 (50.0)	13 (61.9)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.104
95% CI for the RR		(0.655, 1.860)
p-value for RR		0.7112
Day 45		
Number of subjects with a response, n (%) [2]	13 (65.0)	13 (61.9)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.849
95% CI for the RR		(0.566, 1.274)
p-value for RR		0.4292

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 15		
Number of subjects with a response, n (%) [2]	16 (47.1)	26 (61.9)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.169
95% CI for the RR		(0.770, 1.776)
p-value for RR		0.4636
Day 45		
Number of subjects with a response, n (%) [2]	17 (50.0)	30 (71.4)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.270
95% CI for the RR		(0.893, 1.806)
p-value for RR		0.1838

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.4.2.1 .2 .2 .6 Beginn der PPD

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 15		
Number of subjects with a response, n (%) [2]	14 (43.8)	21 (65.6)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.370
95% CI for the RR		(0.875, 2.144)
p-value for RR		0.1687
Day 45		
Number of subjects with a response, n (%) [2]	15 (46.9)	24 (75.0)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.461
95% CI for the RR		(0.986, 2.165)
p-value for RR		0.0588

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 15		
Number of subjects with a response, n (%) [2]	22 (51.2)	26 (59.1)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.053
95% CI for the RR		(0.734, 1.512)
p-value for RR		0.7795
Day 45		
Number of subjects with a response, n (%) [2]	23 (53.5)	26 (59.1)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.007
95% CI for the RR		(0.729, 1.391)
p-value for RR		0.9652

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.4.2.1 .2 .2 .7 PPD in der Familie

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 15		
Number of subjects with a response, n (%) [2]	7 (70.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.759
95% CI for the RR		(0.420, 1.372)
p-value for RR		0.3614
Day 45		
Number of subjects with a response, n (%) [2]	6 (60.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.759
95% CI for the RR		(0.376, 1.533)
p-value for RR		0.4422

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 15		
Number of subjects with a response, n (%) [2]	29 (44.6)	40 (60.6)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.251
95% CI for the RR		(0.916, 1.709)
p-value for RR		0.1592
Day 45		
Number of subjects with a response, n (%) [2]	32 (49.2)	44 (66.7)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.247
95% CI for the RR		(0.959, 1.622)
p-value for RR		0.0994

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.4.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 15		
Number of subjects with a response, n (%) [2]	30 (50.8)	41 (62.1)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.127
95% CI for the RR		(0.834, 1.523)
p-value for RR		0.4357
Day 45		
Number of subjects with a response, n (%) [2]	32 (54.2)	44 (66.7)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.134
95% CI for the RR		(0.877, 1.466)
p-value for RR		0.3377

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 15		
Number of subjects with a response, n (%) [2]	6 (37.5)	6 (60.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.658
95% CI for the RR		(0.890, 3.087)
p-value for RR		0.1111
Day 45		
Number of subjects with a response, n (%) [2]	6 (37.5)	6 (60.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.658
95% CI for the RR		(0.843, 3.259)
p-value for RR		0.1428

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

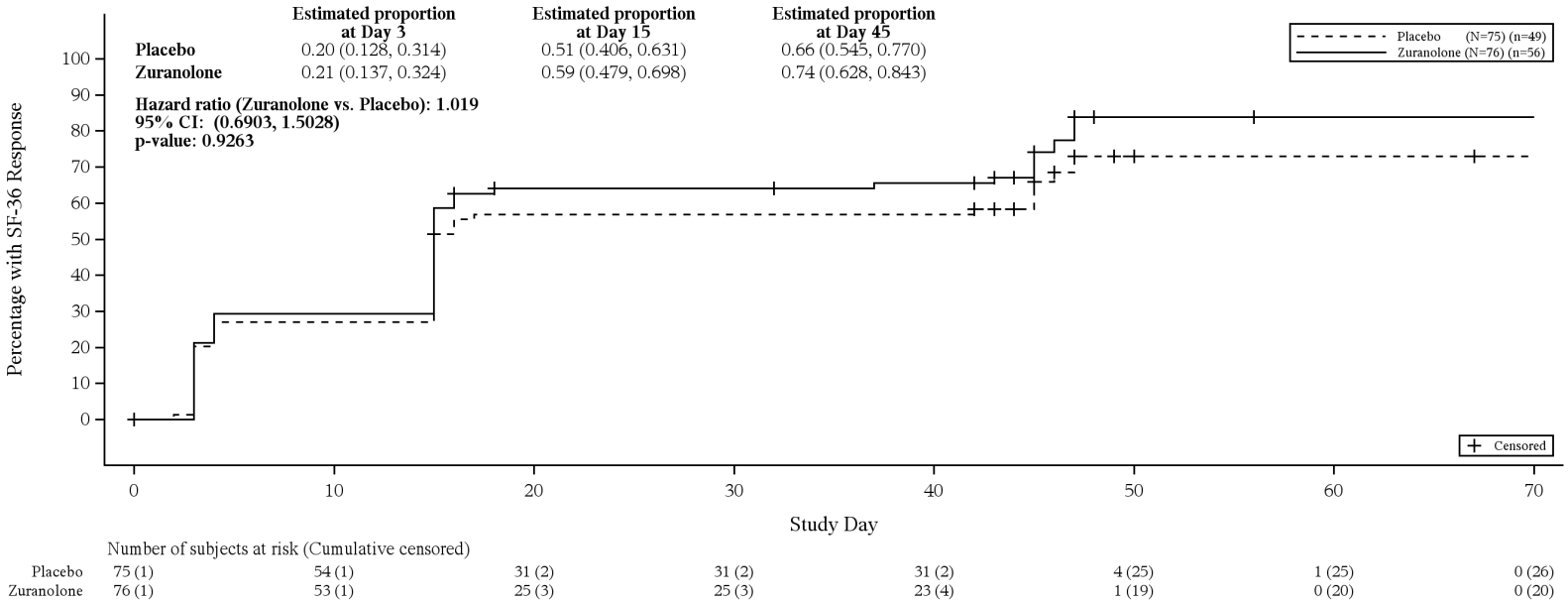
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-201-by.sas:t-sf36-rp-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.4.2.2 TTE-Analysen

2.4.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-ovr.sas:f-sf36-rp-resp15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	49 (65.3)	56 (73.7)
Time to first SF-36 Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 45.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	46.0 (37.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.019
95% CI for the HR		(0.6903 , 1.5028)
p-value for the HR		0.9263

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-ovr.sas:t-sf36-rp-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.4.2.2 .2 Subgruppen

2.4.2.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	49 (65.3)	56 (73.7)	
Age Group (years)			
18 - 24, n / N (%)	15/25 (60.0)	15/17 (88.2)	0.6217
25 - 45, n / N (%)	34/50 (68.0)	41/59 (69.5)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	13/22 (59.1)	23/30 (76.7)	0.7703
>=28, n / N (%)	36/53 (67.9)	33/46 (71.7)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	23/32 (71.9)	25/31 (80.6)	0.5884
White, n / N (%)	23/40 (57.5)	30/44 (68.2)	
Antidepressant Use at Baseline			
Yes, n / N (%)	9/13 (69.2)	13/16 (81.3)	0.6703
No, n / N (%)	40/62 (64.5)	43/60 (71.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-int.sas:t-sf36-rp-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	10/21 (47.6)	8/13 (61.5)	0.1266(a)
25-29.9, n / N (%)	14/20 (70.0)	15/21 (71.4)	0.0340(b)
>=30, n / N (%)	25/34 (73.5)	33/42 (78.6)	0.5896(c)
Onset of PPD			
3rd Trimester, n / N (%)	20/32 (62.5)	27/32 (84.4)	0.5170
Postpartum, n / N (%)	29/43 (67.4)	29/44 (65.9)	
Family History of PPD			
Yes, n / N (%)	8/10 (80.0)	7/10 (70.0)	0.4598
No/Unknown, n / N (%)	41/65 (63.1)	49/66 (74.2)	
History of PPD			
1st Episode, n / N (%)	39/59 (66.1)	50/66 (75.8)	0.7451
Recurrent Episode, n / N (%)	10/16 (62.5)	6/10 (60.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	5/8 (62.5)	6/10 (60.0)	NA
>=20, n / N (%)	44/67 (65.7)	50/66 (75.8)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-int.sas:t-sf36-rp-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.4.2.2 .2 .2 Subgruppenanalysen

2.4.2.2 .2 .2 .1 Alter

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	15 (60.0)	15 (88.2)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	3.0 (3.0 , 15.0)
50th percentile - median (95% CI)	17.0 (15.0, NE)	15.0 (3.0 , 16.0)
75th percentile - Q3 (95% CI)	NE (42.0, NE)	16.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.521
95% CI for the HR		(0.6381 , 3.6260)
p-value for the HR		0.3439

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	34 (68.0)	41 (69.5)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 45.0)	15.0 (15.0 , 43.0)
75th percentile - Q3 (95% CI)	47.0 (45.0, NE)	47.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.977
95% CI for the HR		(0.6196 , 1.5409)
p-value for the HR		0.9206

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.4.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	13 (59.1)	23 (76.7)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0, NE)	15.0 (4.0 , 43.0)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	45.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.832
95% CI for the HR		(0.3981 , 1.7377)
p-value for the HR		0.6241

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	36 (67.9)	33 (71.7)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.5 (15.0 , 45.0)	15.0 (15.0 , 37.0)
75th percentile - Q3 (95% CI)	47.0 (45.0, NE)	47.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.077
95% CI for the HR		(0.6711 , 1.7295)
p-value for the HR		0.7577

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.4.2.2 .2 .2 .3 Abstammung

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	23 (71.9)	25 (80.6)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 16.0)	15.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	47.0 (15.0, NE)	46.0 (16.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.834
95% CI for the HR		(0.4658 , 1.4928)
p-value for the HR		0.5410

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	23 (57.5)	30 (68.2)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	9.5 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	17.0 (15.0, NE)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.997
95% CI for the HR		(0.5620 , 1.7675)
p-value for the HR		0.9908

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.4.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	9 (69.2)	13 (81.3)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 42.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	42.0 (3.0 , 45.0)	15.0 (4.0 , 37.0)
75th percentile - Q3 (95% CI)	45.0 (16.0, NE)	45.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.291
95% CI for the HR		(0.5456 , 3.0552)
p-value for the HR		0.5609

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	40 (64.5)	43 (71.7)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 45.0)	15.0 (15.0 , 18.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	47.0 (18.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.951
95% CI for the HR		(0.6138 , 1.4737)
p-value for the HR		0.8223

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.4.2.2 .2 .2 .5 BMI

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	10 (47.6)	8 (61.5)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 15.0)	3.0 (3.0 , 15.0)
50th percentile - median (95% CI)	16.0 (15.0, NE)	15.0 (3.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.001
95% CI for the HR		(1.0878 , 8.2795)
p-value for the HR		0.0338

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	14 (70.0)	15 (71.4)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	9.5 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.5 (4.0 , 47.0)	15.0 (4.0 , 47.0)
75th percentile - Q3 (95% CI)	47.0 (16.0, NE)	47.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.899
95% CI for the HR		(0.4250 , 1.9014)
p-value for the HR		0.7805

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	25 (73.5)	33 (78.6)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (3.0 , 45.0)	15.0 (15.0 , 18.0)
75th percentile - Q3 (95% CI)	45.0 (16.0, NE)	45.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.791
95% CI for the HR		(0.4617 , 1.3565)
p-value for the HR		0.3948

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.4.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	20 (62.5)	27 (84.4)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (4.0 , 47.0)	15.0 (3.0 , 18.0)
75th percentile - Q3 (95% CI)	47.0 (45.0, NE)	43.0 (15.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.202
95% CI for the HR		(0.6610 , 2.1865)
p-value for the HR		0.5463

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	29 (67.4)	29 (65.9)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 45.0)	15.0 (15.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	47.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.892
95% CI for the HR		(0.5311 , 1.4972)
p-value for the HR		0.6646

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.4.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	8 (80.0)	7 (70.0)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	3.0 (3.0 , 15.0)
50th percentile - median (95% CI)	9.5 (3.0 , 15.0)	15.0 (3.0, NE)
75th percentile - Q3 (95% CI)	15.0 (4.0, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.724
95% CI for the HR		(0.2321 , 2.2612)
p-value for the HR		0.5788

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	41 (63.1)	49 (74.2)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	16.0 (15.0 , 45.0)	15.0 (15.0 , 18.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	46.0 (37.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.074
95% CI for the HR		(0.7027 , 1.6423)
p-value for the HR		0.7407

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.4.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	39 (66.1)	50 (75.8)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 45.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	45.0 (16.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.068
95% CI for the HR		(0.6974 , 1.6349)
p-value for the HR		0.7628

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	10 (62.5)	6 (60.0)
Time to first Role-Physical Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	15.0 (3.0 , 18.0)
50th percentile - median (95% CI)	16.0 (4.0, NE)	16.5 (3.0, NE)
75th percentile - Q3 (95% CI)	47.0 (16.0, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.882
95% CI for the HR		(0.3127 , 2.4891)
p-value for the HR		0.8128

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

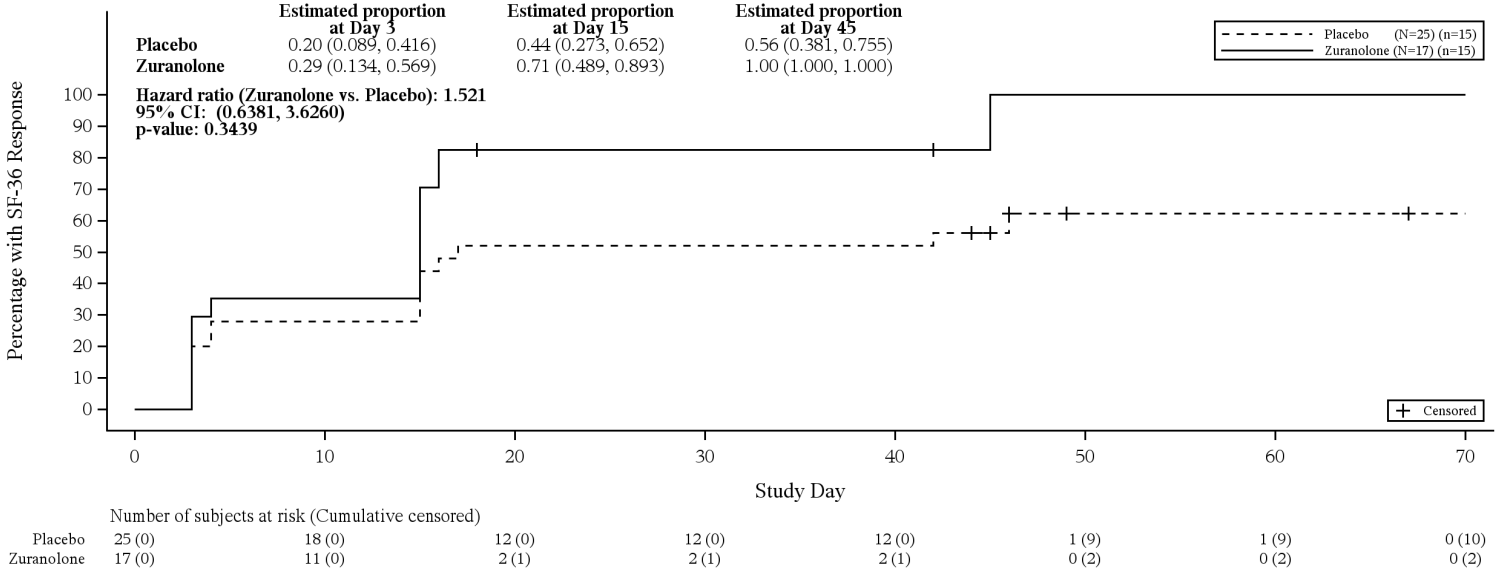
Source: biib125/v_a/germany_amnog/t-sf36-rp-resp15-tte-201-by.sas:t-sf36-rp-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.4.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

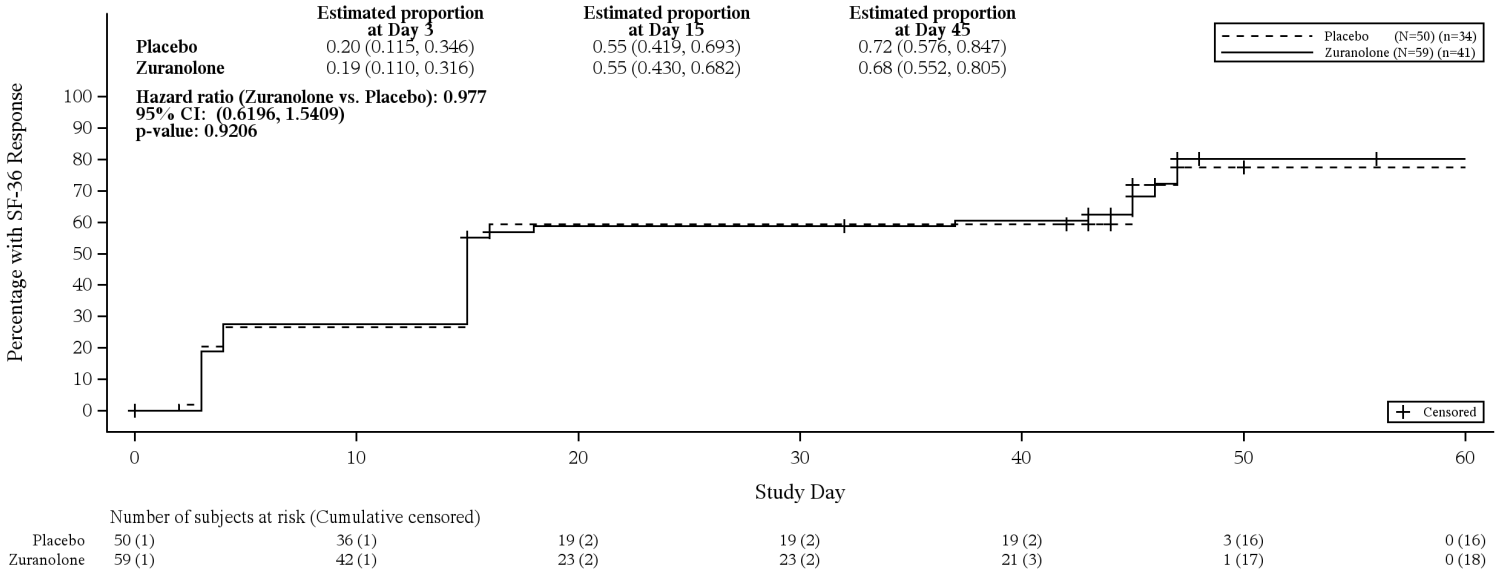
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

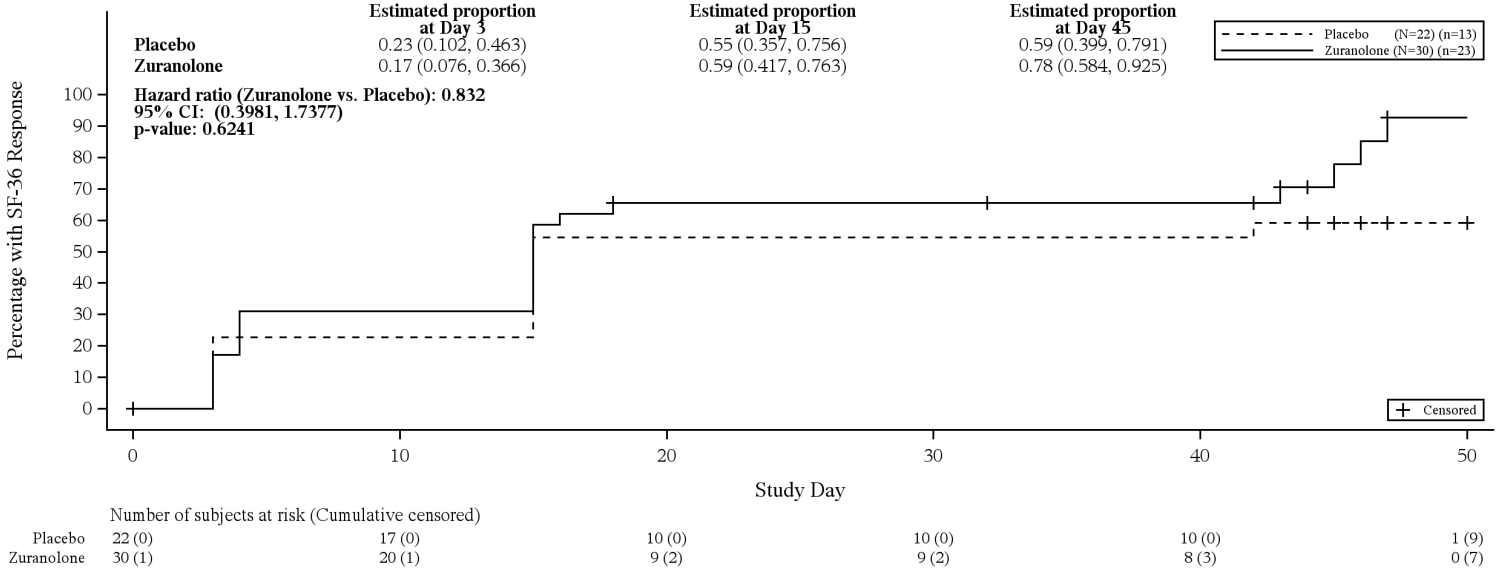
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	17 (0)	10 (0)	10 (0)	10 (0)	1 (9)
Zuranolone	30 (1)	20 (1)	9 (2)	9 (2)	8 (3)	0 (7)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

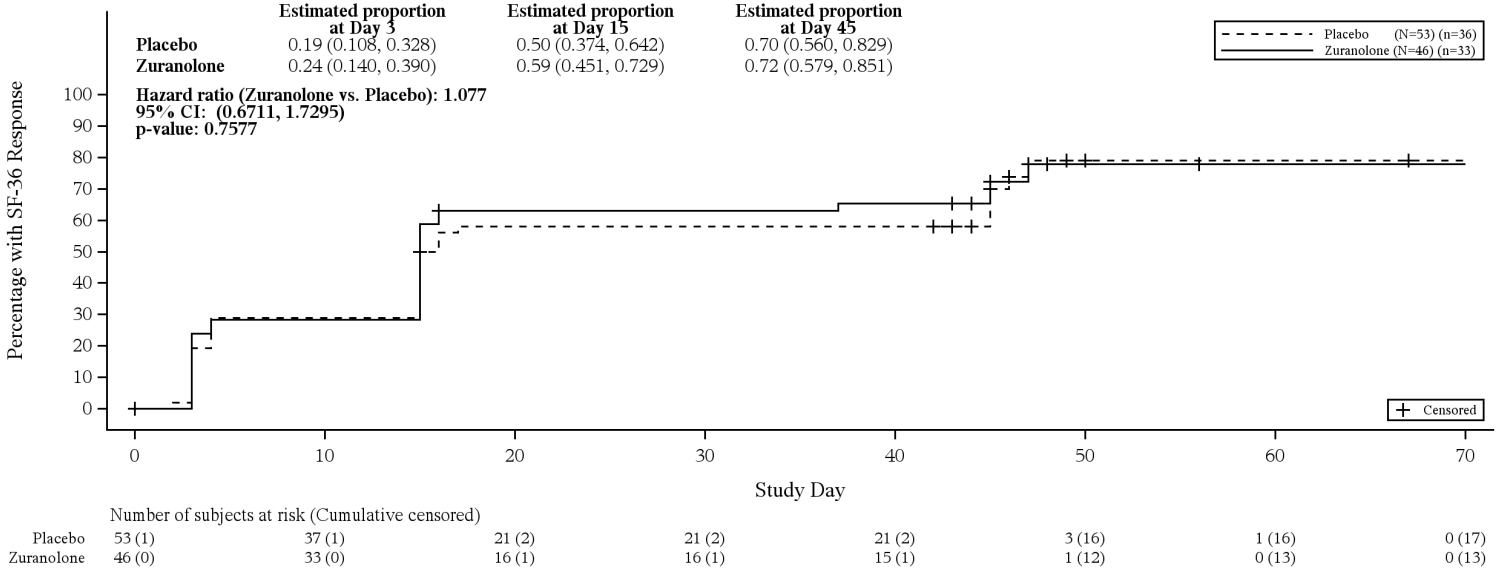
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

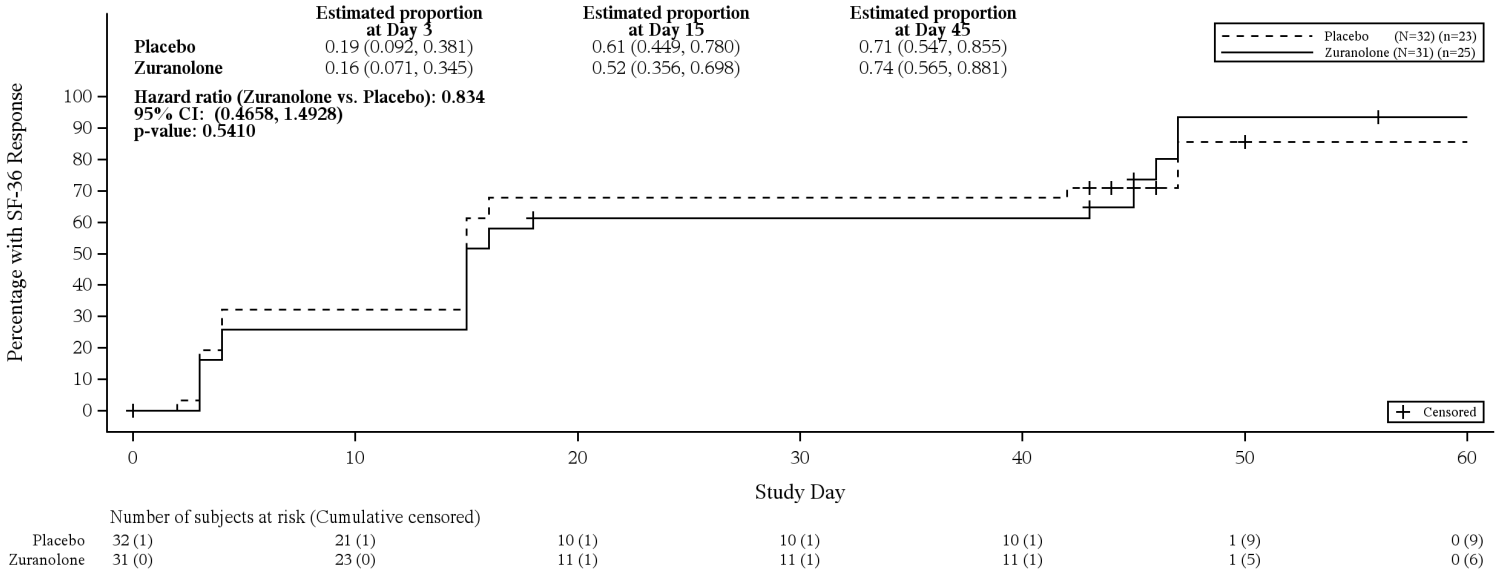
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

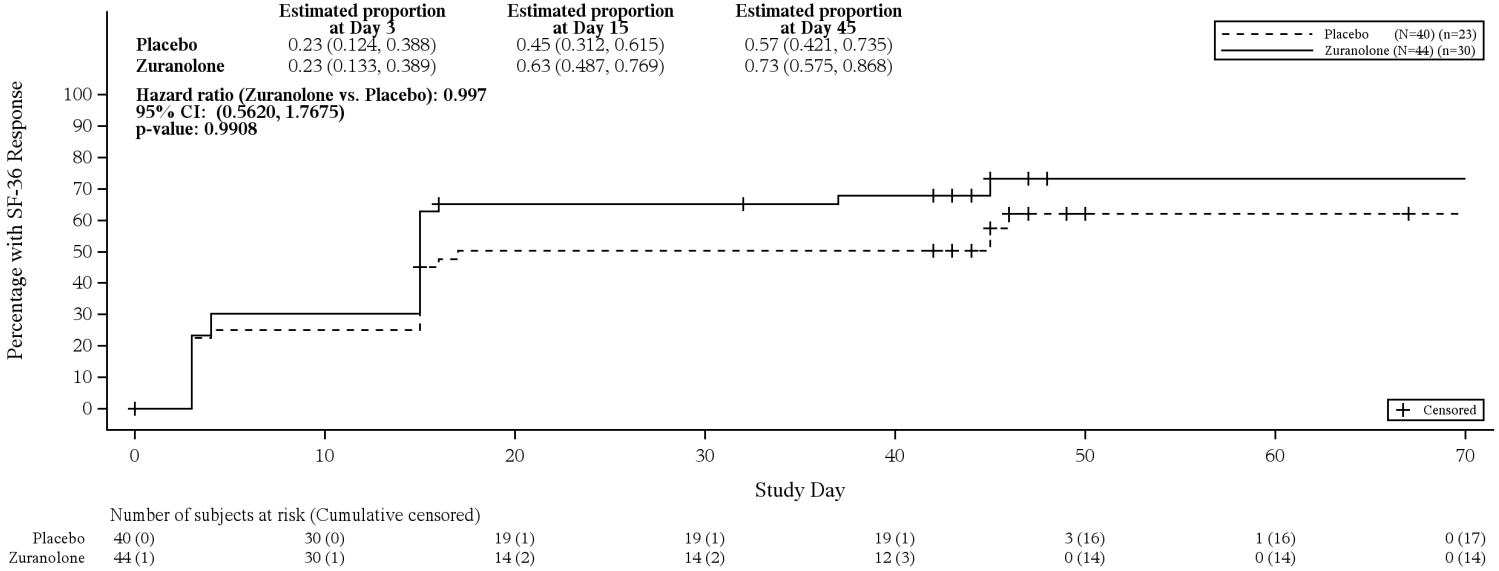
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

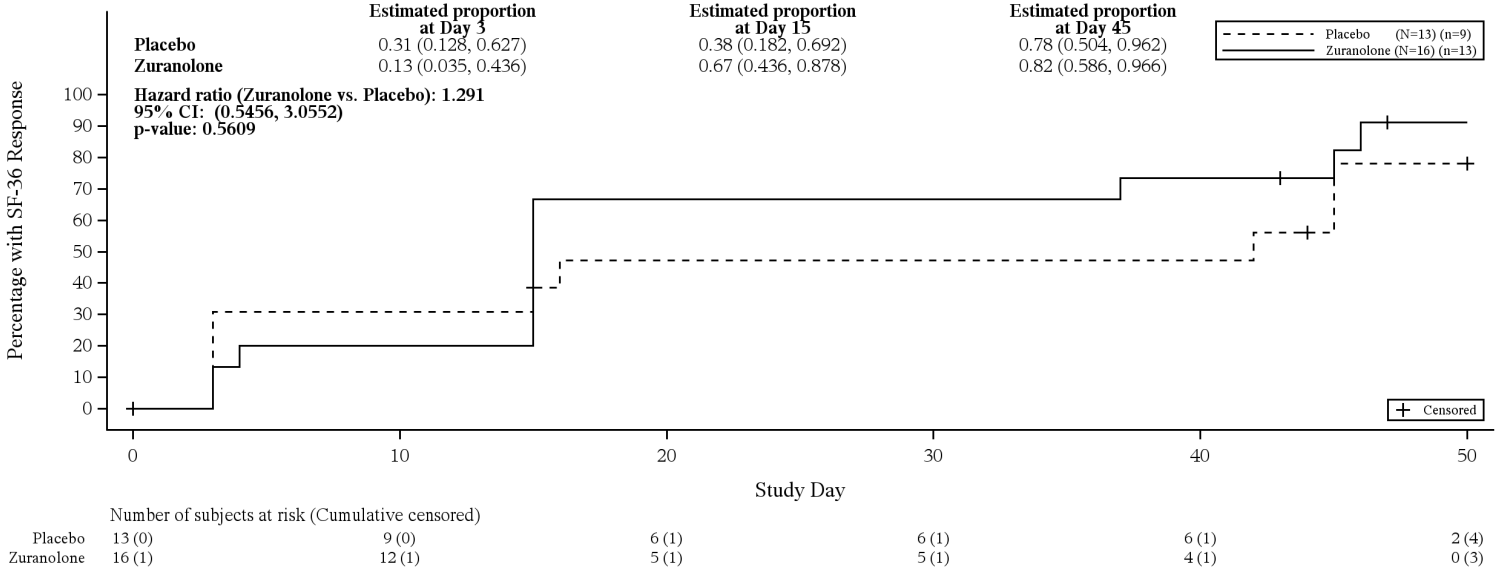
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 7 of 17

Antidepressant Use at Baseline = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

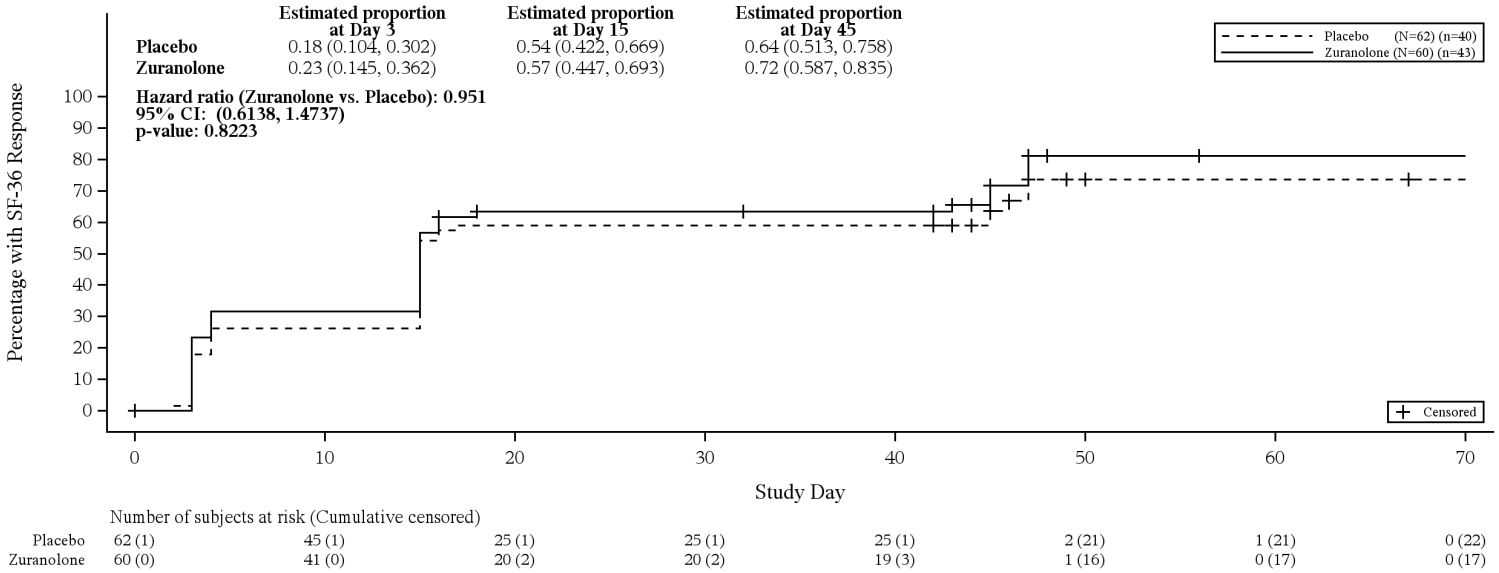
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

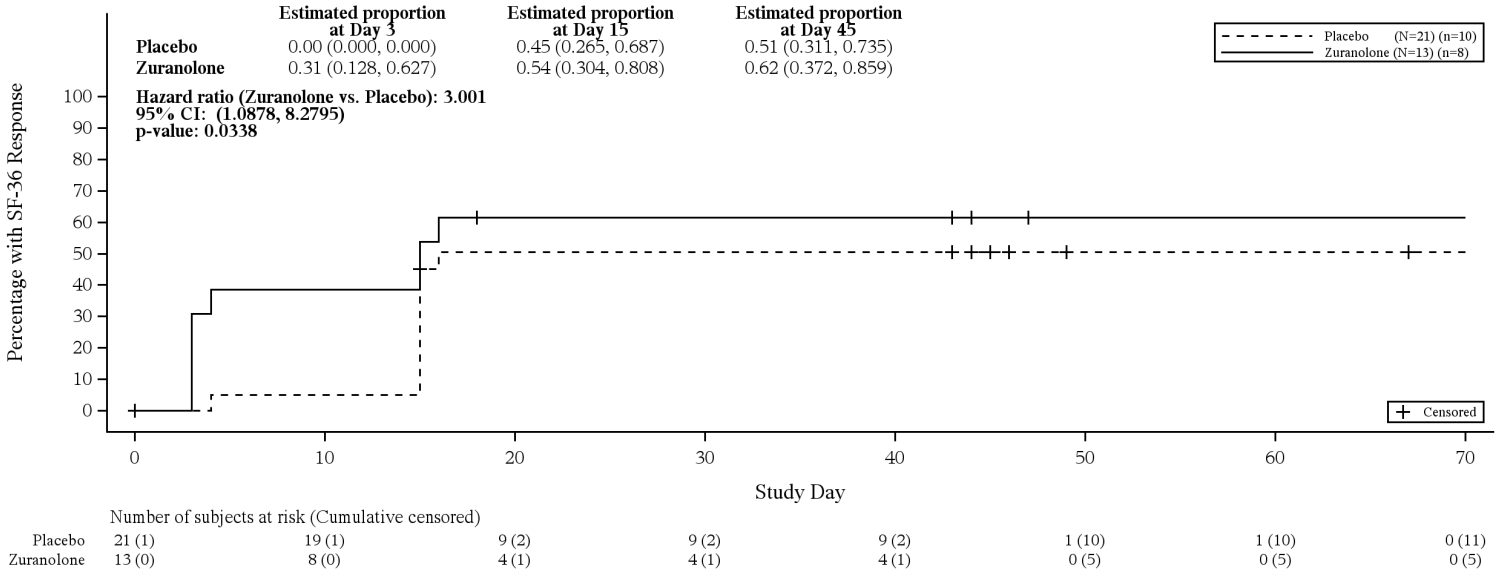
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

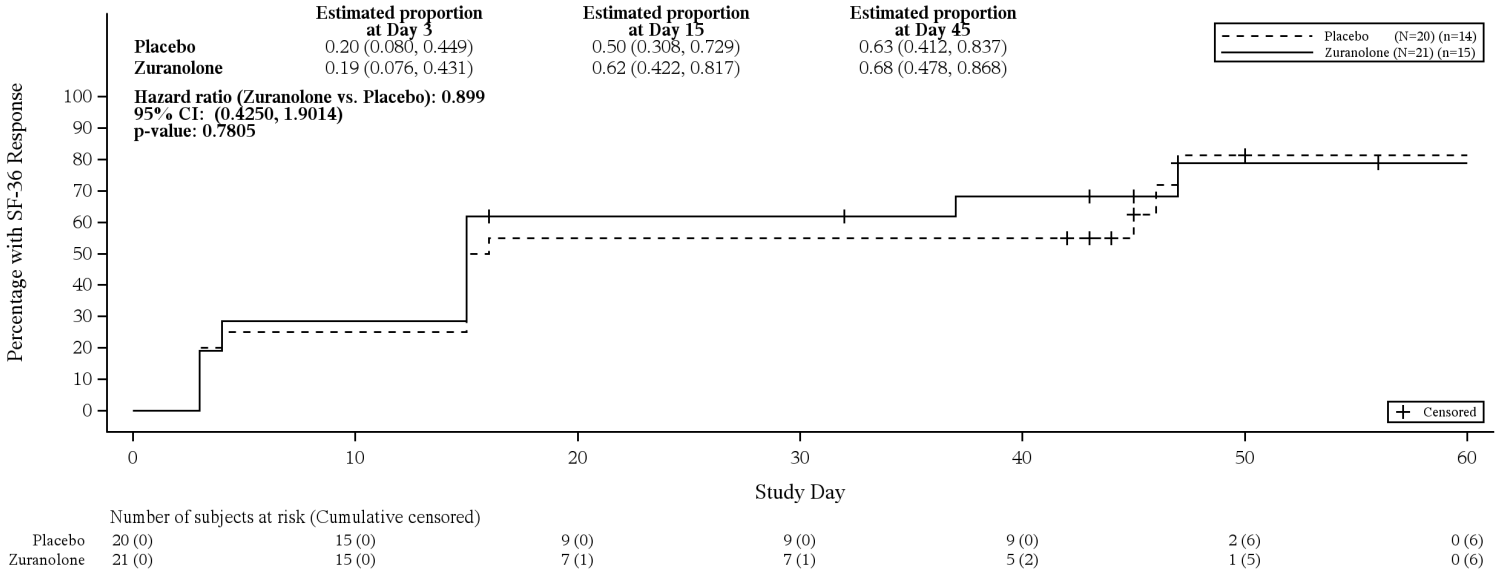
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

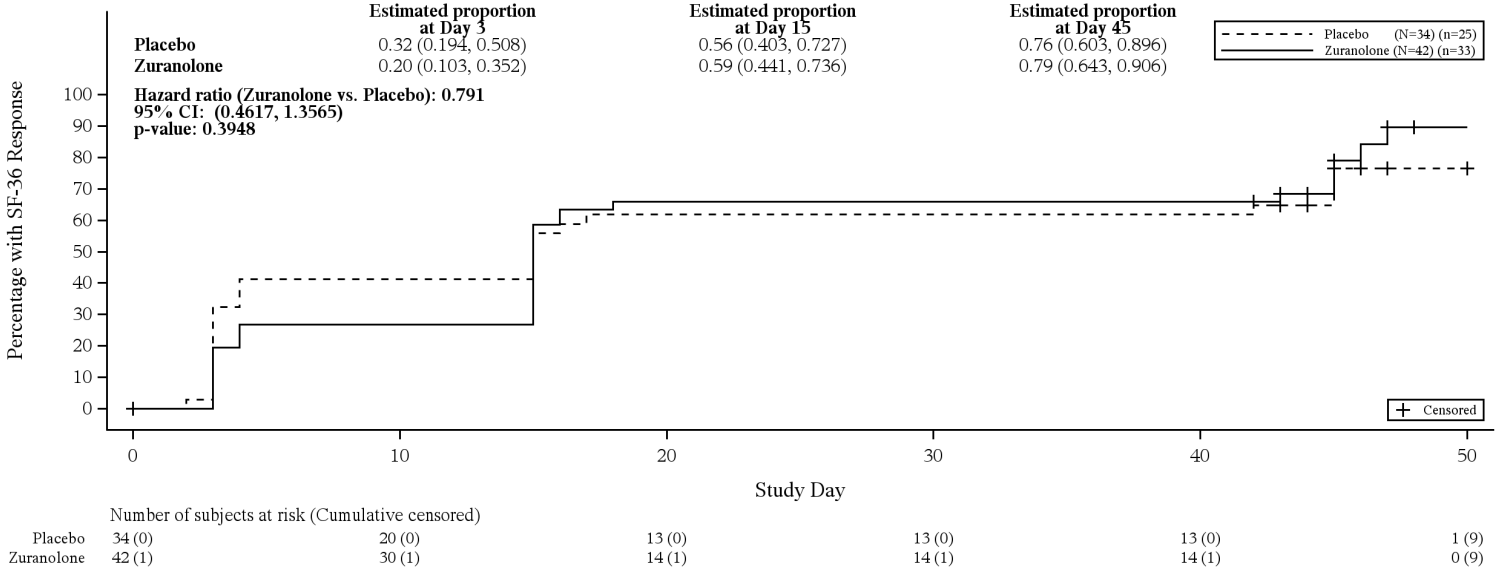
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Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Number of subjects at risk (Cumulative censored)

Placebo	34 (0)	20 (0)	13 (0)	13 (0)	13 (0)	1 (9)
Zuranolone	42 (1)	30 (1)	14 (1)	14 (1)	14 (1)	0 (9)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

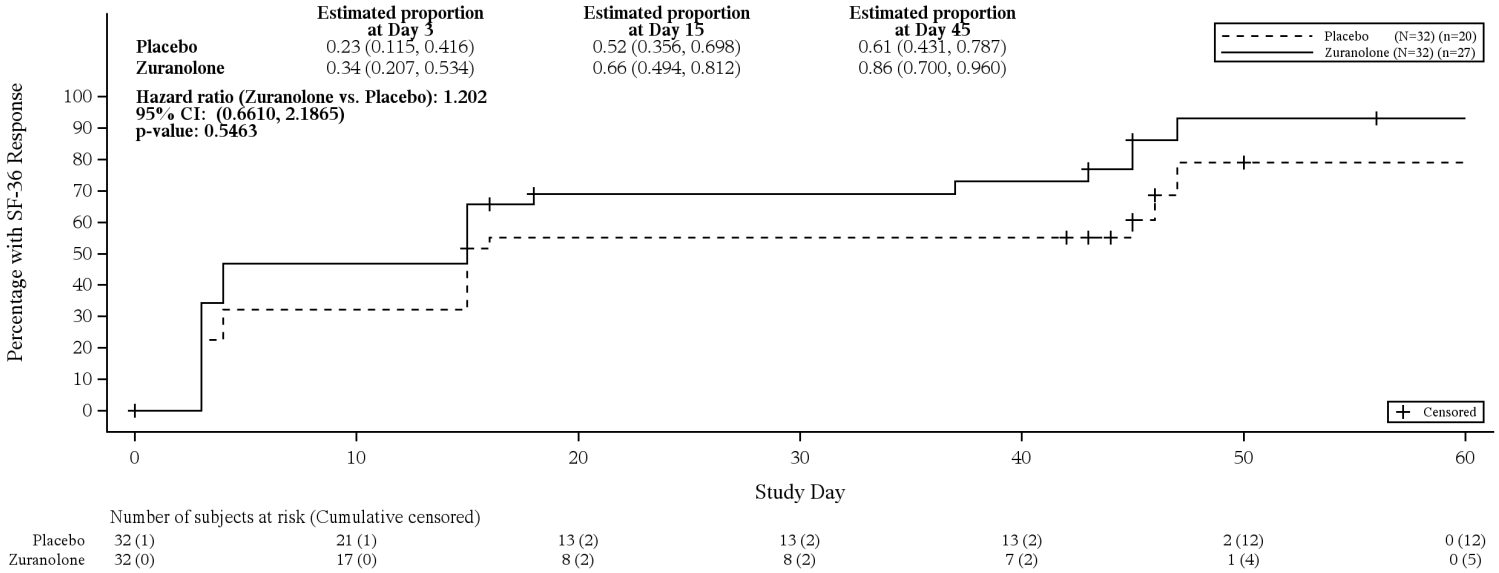
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

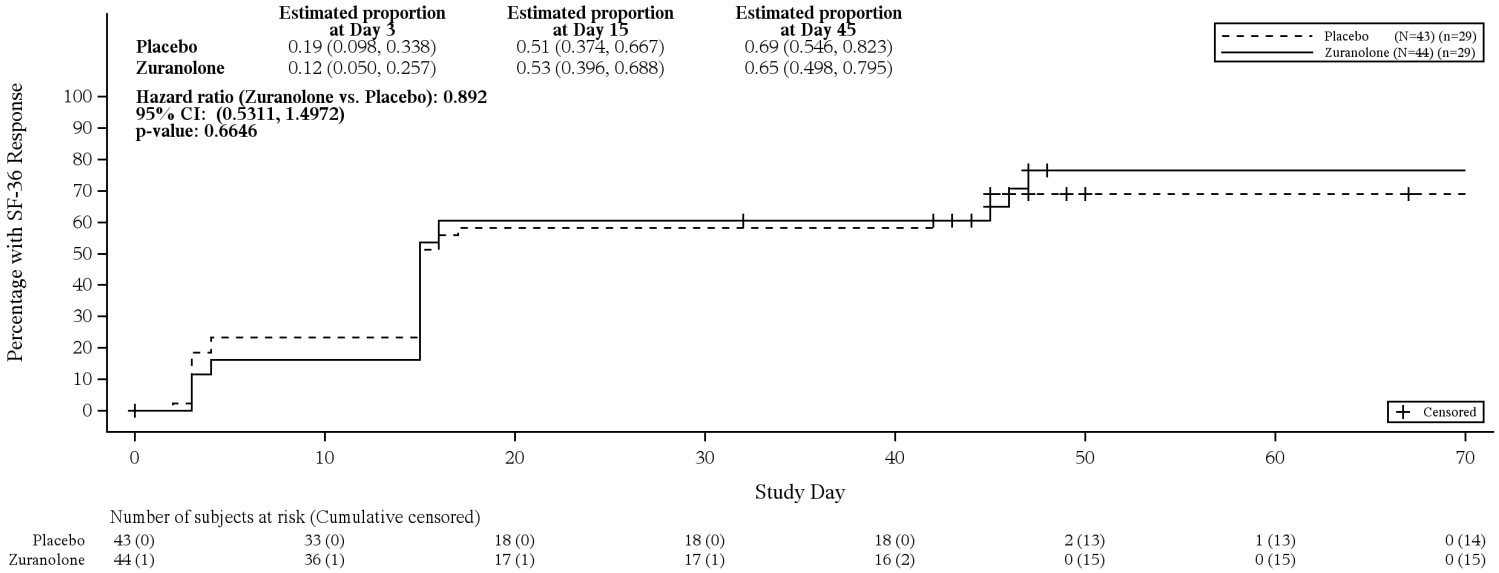
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

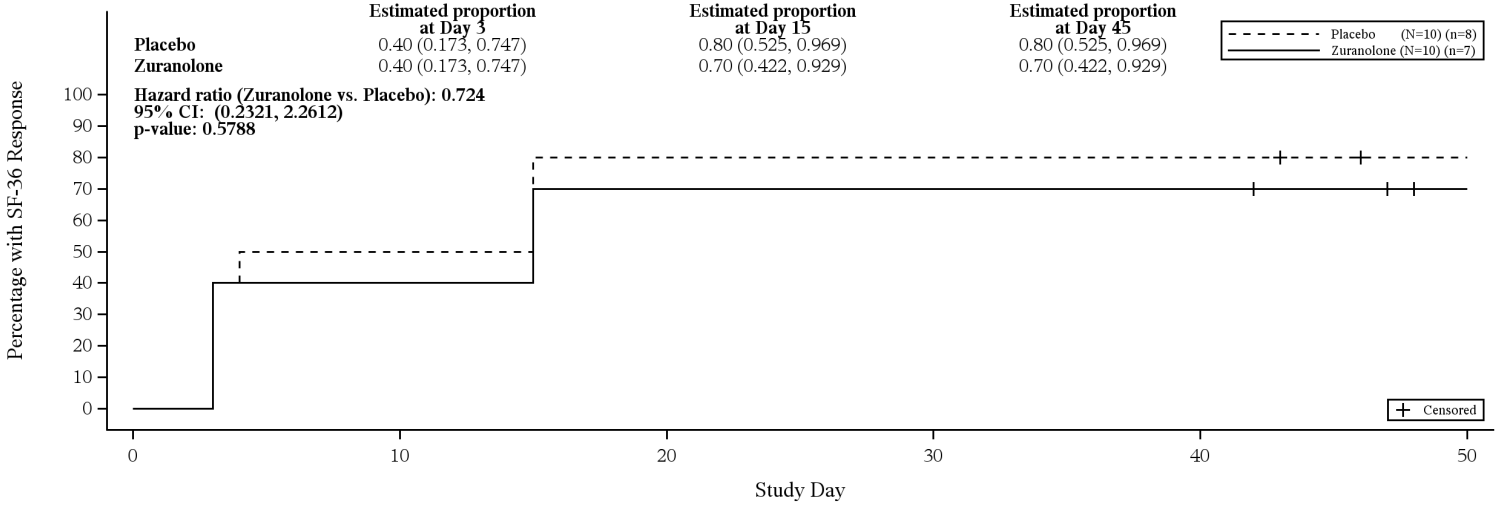
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

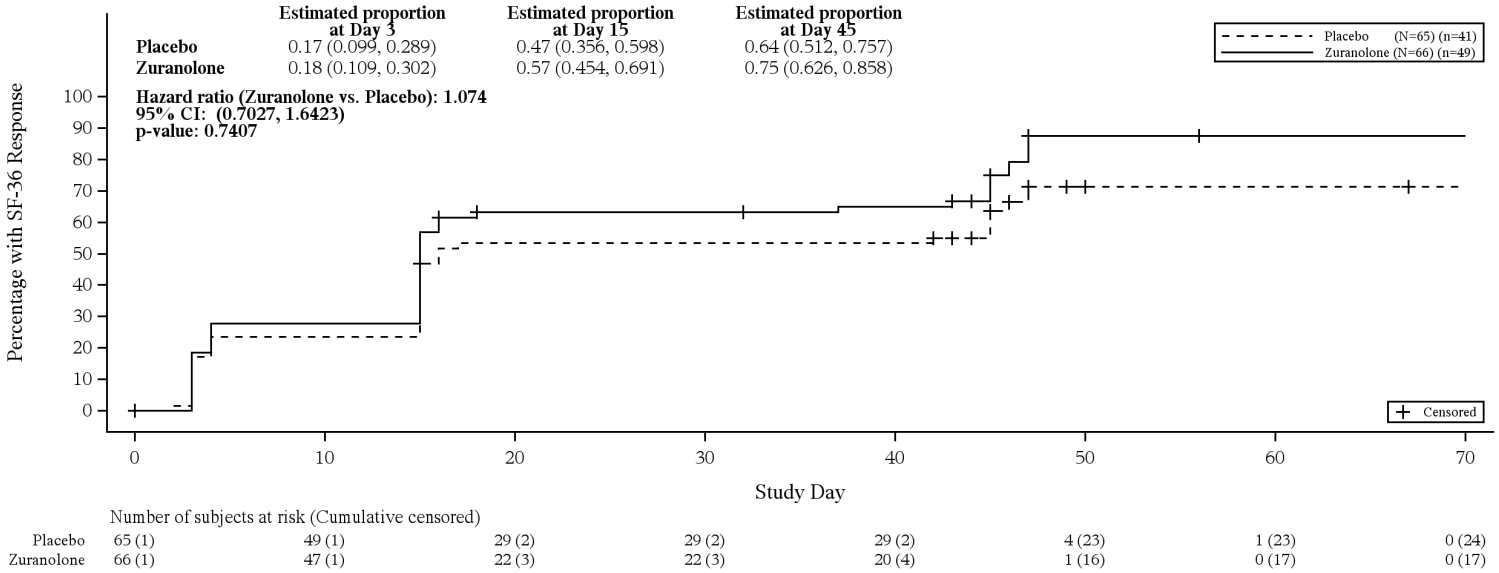
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 15 of 17

Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

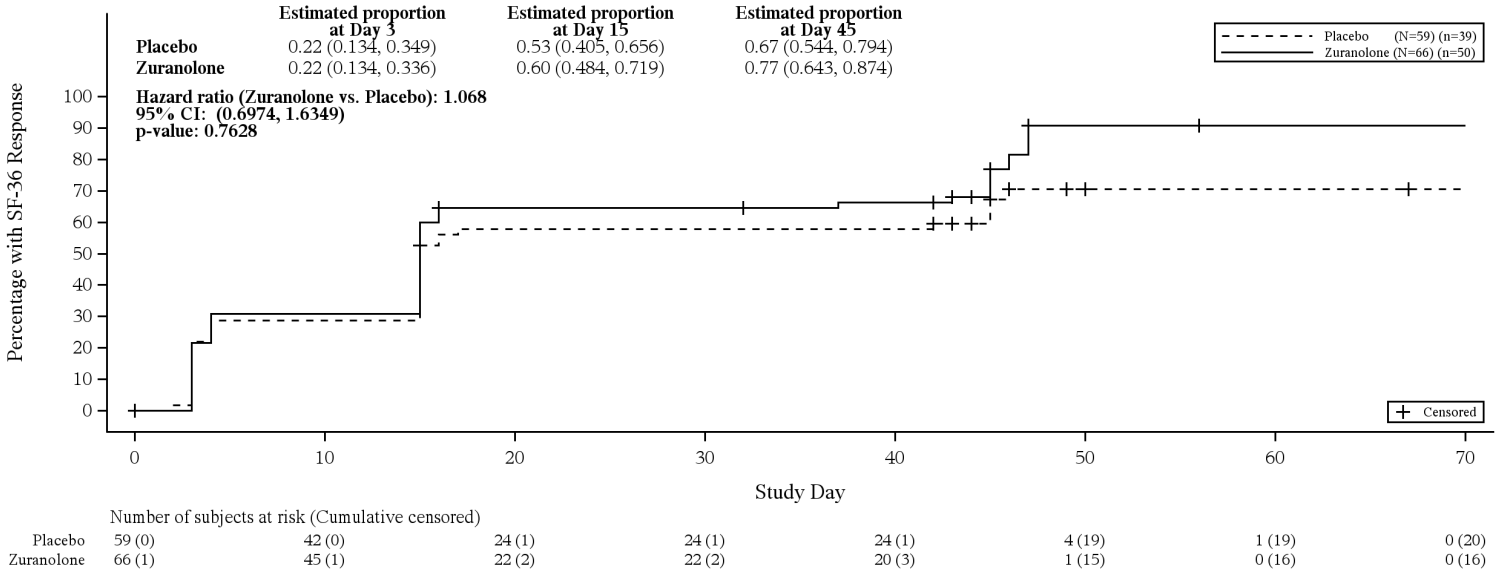
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

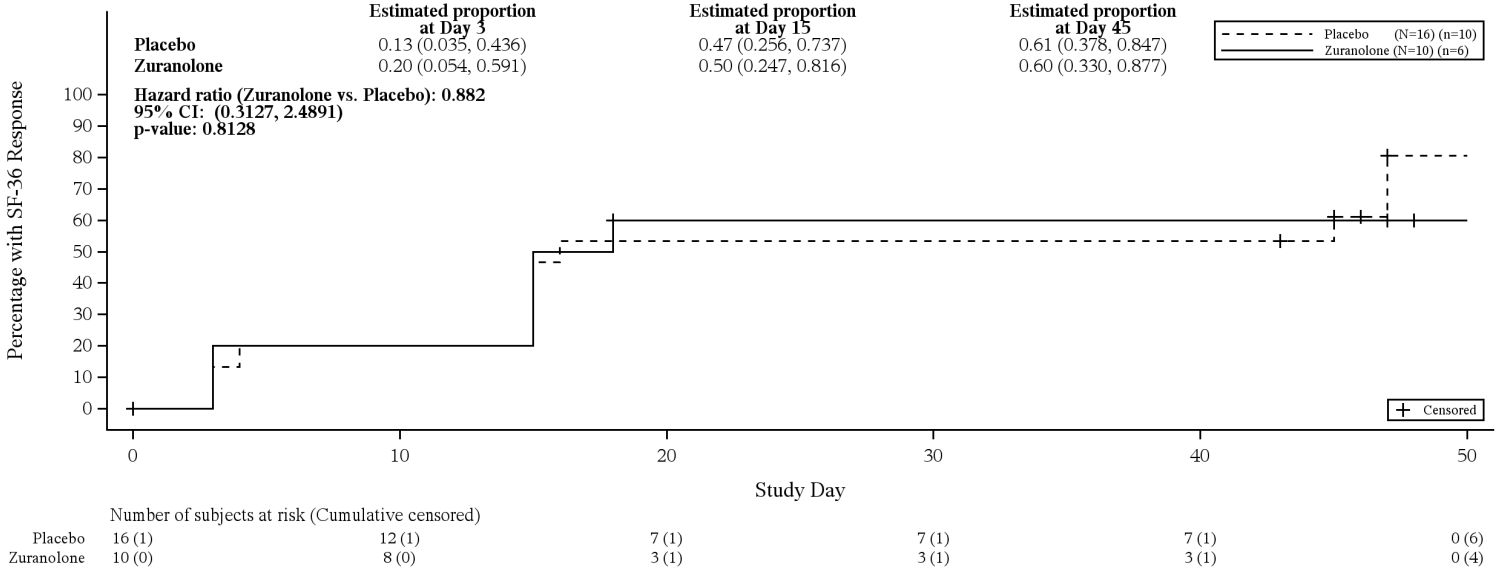
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-rp-resp15-tte-201-by.sas:f-sf36-rp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

2.4.3 Verschlechterung

2.4.3.1 Responder-Analysen

2.4.3.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with worsening, n (%) [2]	6 (8.0)	5 (6.6)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.932
95% CI for the RR		(0.308, 2.824)
p-value for RR		0.9016
OR - Odds Ratio (Zuranolone vs. Placebo)		0.954
95% CI for the OR		(0.269, 3.381)
p-value for OR		0.9421
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score (for the respective parameter) worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-wors15-201-ovr.sas:t-sf36-rp-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	5 (6.7)	3 (3.9)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.692
95% CI for the RR		(0.174, 2.762)
p-value for RR		0.6024
OR - Odds Ratio (Zuranolone vs. Placebo)		0.669
95% CI for the OR		(0.147, 3.039)
p-value for OR		0.6030
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Physical subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing SF-36 Role-Physical subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Physical subscale score (for the respective parameter) worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-rp-wors15-201-ovr.sas:t-sf36-rp-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.4.3.1 .2 Subgruppen

2.4.3.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	6 (8.0)	5 (6.6)	
Number of subjects with response at Day 45, n (%)	5 (6.7)	3 (3.9)	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	1/25 (4.0)	0/17	
25 - 45, n / N (%)	5/50 (10.0)	5/59 (8.5)	
Day 45			
18 - 24, n / N (%)	2/25 (8.0)	0/17	
25 - 45, n / N (%)	3/50 (6.0)	3/59 (5.1)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-wors15-201-int.sas:t-sf36-rp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	2/22 (9.1)	1/30 (3.3)	
>=28, n / N (%)	4/53 (7.5)	4/46 (8.7)	
Day 45			
<28, n / N (%)	1/22 (4.5)	0/30	
>=28, n / N (%)	4/53 (7.5)	3/46 (6.5)	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	3/32 (9.4)	2/31 (6.5)	
White, n / N (%)	3/40 (7.5)	3/44 (6.8)	
Day 45			
Black or African American, n / N (%)	1/32 (3.1)	1/31 (3.2)	
White, n / N (%)	4/40 (10.0)	2/44 (4.5)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-wors15-201-int.sas:t-sf36-rp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	6/62 (9.7)	5/60 (8.3)	
Day 45			
Yes, n / N (%)	1/13 (7.7)	0/16	
No, n / N (%)	4/62 (6.5)	3/60 (5.0)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-wors15-201-int.sas:t-sf36-rp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	0/21	0/13	
25-29.9, n / N (%)	3/20 (15.0)	2/21 (9.5)	
>=30, n / N (%)	3/34 (8.8)	3/42 (7.1)	
Day 45			
<=24.9, n / N (%)	3/21 (14.3)	0/13	
25-29.9, n / N (%)	2/20 (10.0)	2/21 (9.5)	
>=30, n / N (%)	0/34	1/42 (2.4)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-wors15-201-int.sas:t-sf36-rp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 5 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	4/32 (12.5)	1/32 (3.1)	
Postpartum, n / N (%)	2/43 (4.7)	4/44 (9.1)	
Day 45			
3rd Trimester, n / N (%)	2/32 (6.3)	2/32 (6.3)	
Postpartum, n / N (%)	3/43 (7.0)	1/44 (2.3)	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	1/10 (10.0)	1/10 (10.0)	
No/Unknown, n / N (%)	5/65 (7.7)	4/66 (6.1)	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	5/65 (7.7)	3/66 (4.5)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-wors15-201-int.sas:t-sf36-rp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Physical Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 6 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	4/59 (6.8)	3/66 (4.5)	
Recurrent Episode, n / N (%)	2/16 (12.5)	2/10 (20.0)	
Day 45			
1st Episode, n / N (%)	4/59 (6.8)	3/66 (4.5)	
Recurrent Episode, n / N (%)	1/16 (6.3)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/8	1/10 (10.0)	
>=20, n / N (%)	6/67 (9.0)	4/66 (6.1)	
Day 45			
<20, n / N (%)	1/8 (12.5)	0/10	
>=20, n / N (%)	4/67 (6.0)	3/66 (4.5)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-wors15-201-int.sas:t-sf36-rp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

2.4.3.1 .2 .2 Subgruppenanalysen

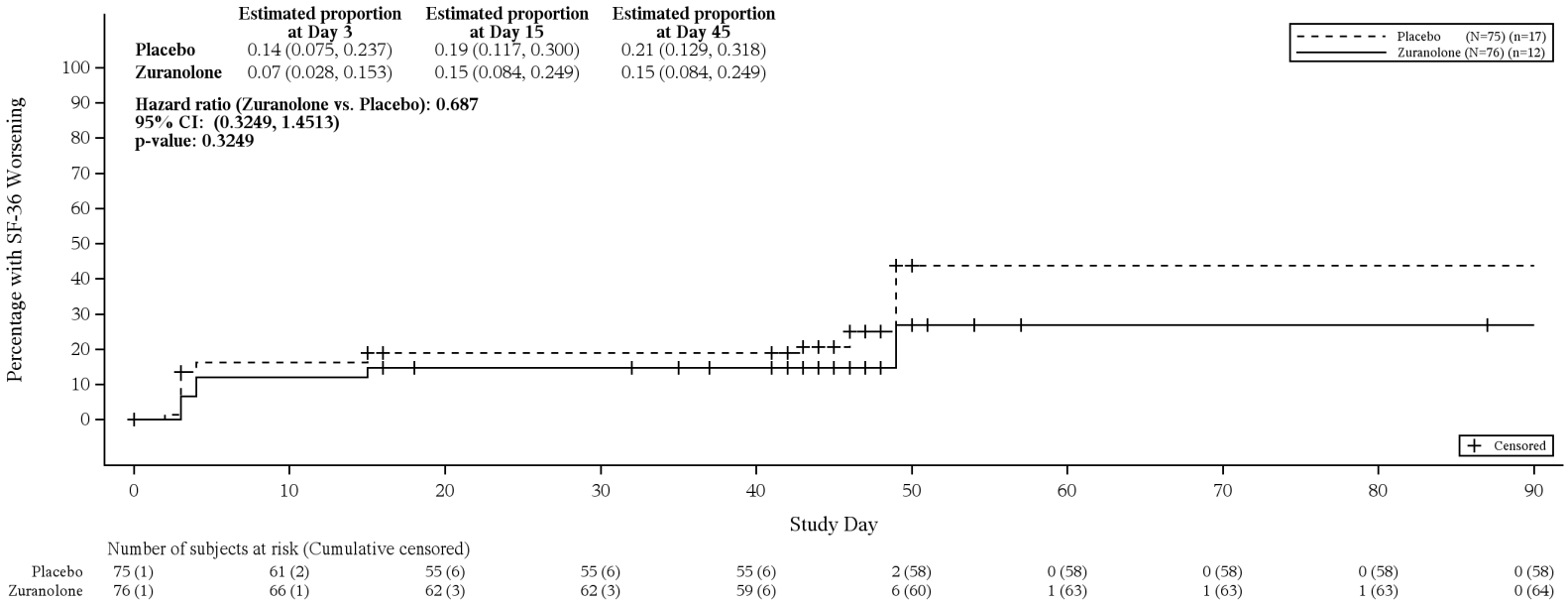
Nicht zutreffend.

2.4.3.2 TTE-Analysen

2.4.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Role-Physical Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening; NE=Not Estimable.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-rp-wors15-tte-201-by.sas:f-sf36-rp-wors15-tte-201-by-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	17 (22.7)	12 (15.8)
Time to first Role-Physical Subscale worsening (days) [3]		
25th percentile - Q1 (95% CI)	49.0 (4.0, NE)	49.0 (49.0, NE)
50th percentile - median (95% CI)	NE (49.0, NE)	NE (49.0, NE)
75th percentile - Q3 (95% CI)	NE (49.0, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.687
95% CI for the HR		(0.3249 , 1.4513)
p-value for the HR		0.3249

NOTE 1: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) worsening. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-rp-wors15-tte-201-ovr.sas:t-sf36-rp-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.4.3.2 .2 Subgruppen

2.4.3.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	17 (22.7)	12 (15.8)	
Age Group (years)			
18 - 24, n / N (%)	6/25 (24.0)	0/17	0.9873
25 - 45, n / N (%)	11/50 (22.0)	12/59 (20.3)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	4/22 (18.2)	2/30 (6.7)	0.6113
>=28, n / N (%)	13/53 (24.5)	10/46 (21.7)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	8/32 (25.0)	6/31 (19.4)	NA
White, n / N (%)	8/40 (20.0)	6/44 (13.6)	
Antidepressant Use at Baseline			
Yes, n / N (%)	2/13 (15.4)	2/16 (12.5)	0.4683
No, n / N (%)	15/62 (24.2)	10/60 (16.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-wors15-tte-201-int.sas:t-sf36-rp-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Physical Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	5/21 (23.8)	0/13	NA(a)
25-29.9, n / N (%)	6/20 (30.0)	4/21 (19.0)	NA(b)
>=30, n / N (%)	6/34 (17.6)	8/42 (19.0)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	6/32 (18.8)	4/32 (12.5)	0.6714
Postpartum, n / N (%)	11/43 (25.6)	8/44 (18.2)	
Family History of PPD			
Yes, n / N (%)	2/10 (20.0)	1/10 (10.0)	0.9866
No/Unknown, n / N (%)	15/65 (23.1)	11/66 (16.7)	
History of PPD			
1st Episode, n / N (%)	11/59 (18.6)	10/66 (15.2)	0.5194
Recurrent Episode, n / N (%)	6/16 (37.5)	2/10 (20.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	2/8 (25.0)	3/10 (30.0)	NA
>=20, n / N (%)	15/67 (22.4)	9/66 (13.6)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-rp-wors15-tte-201-int.sas:t-sf36-rp-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.4.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

2.4.3.2 .2 .3 Kaplan-Meier-Plots

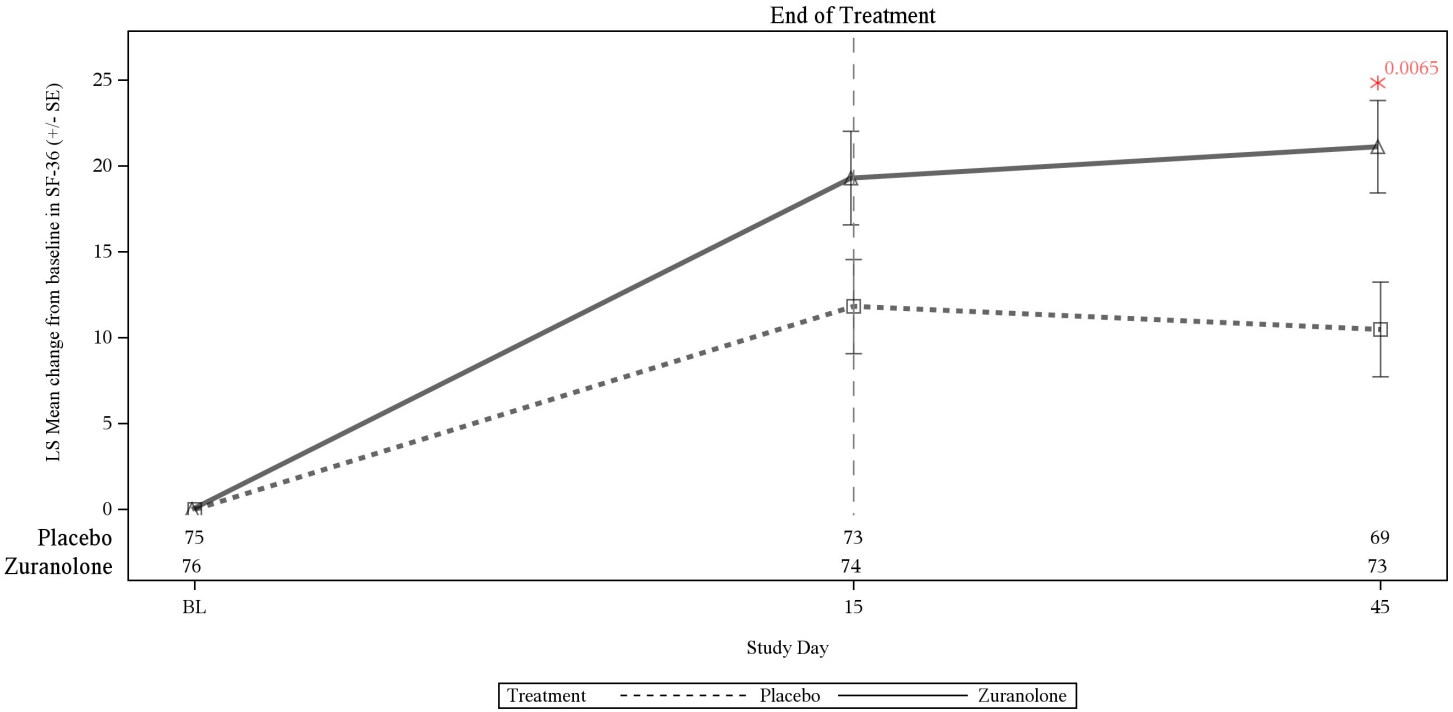
Nicht zutreffend.

2.5 körperliche Schmerzen

2.5.1 MMRM

2.5.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain: 217-PPD-201B - ITT population
Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-ovr.sas:f-sf36-bp-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale: 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	11.82 (2.737)	19.29 (2.715)
95% CI for the LS Mean	6.41, 17.24	13.93, 24.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.47 (3.857)
95% CI for the LS Mean		-0.16, 15.09
p-value		0.0548
Hedges' g (Zuranolone vs. Placebo)		0.318
95% CI for Hedges' g		-0.0076, 0.6431
Day 45		
n	69	73
LS Mean (SE)	10.48 (2.763)	21.13 (2.694)
95% CI for the LS Mean	5.01, 15.94	15.81, 26.46
Difference (Zuranolone - Placebo)		
LS Mean (SE)		10.66 (3.860)
95% CI for the LS Mean		3.02, 18.29
p-value		0.0065
Hedges' g (Zuranolone vs. Placebo)		0.461
95% CI for Hedges' g		0.1276, 0.7944

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-ovr.sas:t-sf36-bp-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.5.1.2 Subgruppen

2.5.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.7584
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.0539
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.4133
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.6787
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-int.sas:t-sf36-bp-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.4145(a)
25-29.9	20	21	0.8872(b)
>=30	34	42	0.2534(c)
Onset of PPD			
3rd Trimester	32	32	0.9235
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.0299
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.0678
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-int.sas:t-sf36-bp-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

2.5.1.2 .2 Subgruppenanalysen

2.5.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	11.99 (5.310)	19.12 (6.467)
95% CI for the LS Mean	1.24, 22.74	6.03, 32.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.13 (8.447)
95% CI for the LS Mean		-9.96, 24.22
p-value		0.4037
Hedges' g (Zuranolone vs. Placebo)		0.260
95% CI for Hedges' g		-0.3582, 0.8791
Day 45		
n	25	16
LS Mean (SE)	6.03 (5.291)	19.91 (6.605)
95% CI for the LS Mean	-4.70, 16.76	6.53, 33.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		13.88 (8.541)
95% CI for the LS Mean		-3.43, 31.19
p-value		0.1126
Hedges' g (Zuranolone vs. Placebo)		0.510
95% CI for Hedges' g		-0.1269, 1.1474

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Age Group: 217-PPD-201B - ITT population

Page: 2 of 2

Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	11.70 (3.262)	19.35 (2.989)
95% CI for the LS Mean	5.23, 18.18	13.43, 25.28
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.65 (4.427)
95% CI for the LS Mean		-1.13, 16.43
p-value		0.0870
Hedges' g (Zuranolone vs. Placebo)		0.336
95% CI for Hedges' g		-0.0506, 0.7227
Day 45		
n	44	57
LS Mean (SE)	12.97 (3.288)	21.50 (2.908)
95% CI for the LS Mean	6.45, 19.49	15.73, 27.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.53 (4.394)
95% CI for the LS Mean		-0.19, 17.25
p-value		0.0551
Hedges' g (Zuranolone vs. Placebo)		0.387
95% CI for Hedges' g		-0.0103, 0.7835

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.5.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 2

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	22.58 (5.157)	15.67 (4.545)
95% CI for the LS Mean	12.20, 32.96	6.52, 24.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-6.91 (6.874)
95% CI for the LS Mean		-20.75, 6.92
p-value		0.3198
Hedges' g (Zuranolone vs. Placebo)		-0.282
95% CI for Hedges' g		-0.8431, 0.2791
Day 45		
n	22	28
LS Mean (SE)	13.86 (5.165)	20.40 (4.553)
95% CI for the LS Mean	3.45, 24.26	11.23, 29.57
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.54 (6.886)
95% CI for the LS Mean		-7.33, 20.41
p-value		0.3472
Hedges' g (Zuranolone vs. Placebo)		0.266
95% CI for Hedges' g		-0.2944, 0.8272

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 2 of 2

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	7.22 (3.133)	21.38 (3.301)
95% CI for the LS Mean	1.00, 13.44	14.82, 27.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		14.16 (4.554)
95% CI for the LS Mean		5.11, 23.20
p-value		0.0025
Hedges' g (Zuranolone vs. Placebo)		0.627
95% CI for Hedges' g		0.2188, 1.0352
Day 45		
n	47	45
LS Mean (SE)	9.08 (3.290)	21.52 (3.375)
95% CI for the LS Mean	2.55, 15.62	14.82, 28.23
Difference (Zuranolone - Placebo)		
LS Mean (SE)		12.44 (4.719)
95% CI for the LS Mean		3.07, 21.82
p-value		0.0099
Hedges' g (Zuranolone vs. Placebo)		0.545
95% CI for Hedges' g		0.1290, 0.9616

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.5.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	17.47 (4.356)	26.54 (4.356)
95% CI for the LS Mean	8.75, 26.19	17.82, 35.26
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.07 (6.172)
95% CI for the LS Mean		-3.28, 21.42
p-value		0.1470
Hedges' g (Zuranolone vs. Placebo)		0.369
95% CI for Hedges' g		-0.1335, 0.8706
Day 45		
n	30	30
LS Mean (SE)	12.16 (4.340)	28.48 (4.340)
95% CI for the LS Mean	3.47, 20.86	19.79, 37.18
Difference (Zuranolone - Placebo)		
LS Mean (SE)		16.32 (6.150)
95% CI for the LS Mean		4.00, 28.64
p-value		0.0103
Hedges' g (Zuranolone vs. Placebo)		0.676
95% CI for Hedges' g		0.1559, 1.1966

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Race Group: 217-PPD-201B - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	7.73 (3.629)	14.28 (3.484)
95% CI for the LS Mean	0.50, 14.95	7.34, 21.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.55 (5.053)
95% CI for the LS Mean		-3.51, 16.61
p-value		0.1987
Hedges' g (Zuranolone vs. Placebo)		0.286
95% CI for Hedges' g		-0.1525, 0.7236
Day 45		
n	36	42
LS Mean (SE)	8.73 (3.750)	15.43 (3.502)
95% CI for the LS Mean	1.26, 16.20	8.45, 22.40
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.70 (5.153)
95% CI for the LS Mean		-3.56, 16.96
p-value		0.1976
Hedges' g (Zuranolone vs. Placebo)		0.292
95% CI for Hedges' g		-0.1552, 0.7398

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.5.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	7.17 (5.088)	14.21 (4.714)
95% CI for the LS Mean	-3.31, 17.64	4.51, 23.91
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.04 (6.987)
95% CI for the LS Mean		-7.34, 21.42
p-value		0.3230
Hedges' g (Zuranolone vs. Placebo)		0.371
95% CI for Hedges' g		-0.3782, 1.1198
Day 45		
n	11	15
LS Mean (SE)	8.87 (6.836)	14.87 (5.904)
95% CI for the LS Mean	-5.24, 22.97	2.66, 27.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.01 (9.066)
95% CI for the LS Mean		-12.72, 24.73
p-value		0.5139
Hedges' g (Zuranolone vs. Placebo)		0.255
95% CI for Hedges' g		-0.5263, 1.0359

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	12.82 (3.168)	20.51 (3.189)
95% CI for the LS Mean	6.55, 19.09	14.19, 26.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.69 (4.495)
95% CI for the LS Mean		-1.21, 16.59
p-value		0.0898
Hedges' g (Zuranolone vs. Placebo)		0.312
95% CI for Hedges' g		-0.0499, 0.6732
Day 45		
n	58	58
LS Mean (SE)	10.99 (3.052)	22.69 (3.052)
95% CI for the LS Mean	4.94, 17.04	16.64, 28.73
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.70 (4.316)
95% CI for the LS Mean		3.14, 20.25
p-value		0.0078
Hedges' g (Zuranolone vs. Placebo)		0.500
95% CI for Hedges' g		0.1302, 0.8694

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.5.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Baseline BMI (kg/m²)
Group: 217-PPD-201B - ITT population

Page: 1 of 3

BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	2.36 (5.732)	15.11 (7.111)
95% CI for the LS Mean	-9.38, 14.09	0.55, 29.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		12.76 (9.134)
95% CI for the LS Mean		-5.94, 31.45
p-value		0.1734
Hedges' g (Zuranolone vs. Placebo)		0.485
95% CI for Hedges' g		-0.2226, 1.1934
Day 45		
n	18	12
LS Mean (SE)	-1.97 (5.336)	7.65 (6.532)
95% CI for the LS Mean	-12.94, 9.00	-5.79, 21.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.62 (8.440)
95% CI for the LS Mean		-7.74, 26.98
p-value		0.2650
Hedges' g (Zuranolone vs. Placebo)		0.413
95% CI for Hedges' g		-0.3246, 1.1511

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	22.00 (5.686)	27.47 (5.628)
95% CI for the LS Mean	10.44, 33.55	16.05, 38.89
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.48 (8.079)
95% CI for the LS Mean		-10.93, 21.88
p-value		0.5024
Hedges' g (Zuranolone vs. Placebo)		0.210
95% CI for Hedges' g		-0.4114, 0.8316
Day 45		
n	20	20
LS Mean (SE)	19.60 (5.786)	25.02 (5.722)
95% CI for the LS Mean	7.85, 31.34	13.41, 36.62
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.42 (8.211)
95% CI for the LS Mean		-11.24, 22.08
p-value		0.5133
Hedges' g (Zuranolone vs. Placebo)		0.205
95% CI for Hedges' g		-0.4168, 0.8260

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	8.98 (3.823)	18.22 (3.429)
95% CI for the LS Mean	1.35, 16.60	11.38, 25.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.24 (5.143)
95% CI for the LS Mean		-1.02, 19.50
p-value		0.0768
Hedges' g (Zuranolone vs. Placebo)		0.416
95% CI for Hedges' g		-0.0476, 0.8789
Day 45		
n	31	41
LS Mean (SE)	9.83 (3.528)	25.12 (3.081)
95% CI for the LS Mean	2.79, 16.87	18.97, 31.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		15.29 (4.694)
95% CI for the LS Mean		5.92, 24.65
p-value		0.0018
Hedges' g (Zuranolone vs. Placebo)		0.767
95% CI for Hedges' g		0.2838, 1.2498

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.5.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	14.28 (4.147)	21.57 (4.078)
95% CI for the LS Mean	5.98, 22.58	13.41, 29.73
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.28 (5.823)
95% CI for the LS Mean		-4.36, 18.93
p-value		0.2158
Hedges' g (Zuranolone vs. Placebo)		0.311
95% CI for Hedges' g		-0.1855, 0.8083
Day 45		
n	29	30
LS Mean (SE)	17.14 (4.453)	27.81 (4.379)
95% CI for the LS Mean	8.22, 26.07	19.04, 36.58
Difference (Zuranolone - Placebo)		
LS Mean (SE)		10.67 (6.247)
95% CI for the LS Mean		-1.85, 23.18
p-value		0.0934
Hedges' g (Zuranolone vs. Placebo)		0.439
95% CI for Hedges' g		-0.0778, 0.9552

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	10.28 (3.593)	17.42 (3.586)
95% CI for the LS Mean	3.13, 17.43	10.29, 24.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.15 (5.082)
95% CI for the LS Mean		-2.97, 17.26
p-value		0.1635
Hedges' g (Zuranolone vs. Placebo)		0.304
95% CI for Hedges' g		-0.1261, 0.7342
Day 45		
n	40	43
LS Mean (SE)	5.76 (3.285)	16.40 (3.182)
95% CI for the LS Mean	-0.78, 12.30	10.07, 22.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		10.64 (4.581)
95% CI for the LS Mean		1.53, 19.76
p-value		0.0227
Hedges' g (Zuranolone vs. Placebo)		0.506
95% CI for Hedges' g		0.0683, 0.9431

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.5.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	18.08 (6.803)	13.09 (6.912)
95% CI for the LS Mean	3.64, 32.53	-1.58, 27.77
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.99 (10.148)
95% CI for the LS Mean		-26.52, 16.54
p-value		0.6295
Hedges' g (Zuranolone vs. Placebo)		-0.211
95% CI for Hedges' g		-1.0897, 0.6682
Day 45		
n	9	10
LS Mean (SE)	28.83 (8.332)	12.19 (8.050)
95% CI for the LS Mean	11.11, 46.55	-5.09, 29.47
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-16.64 (12.030)
95% CI for the LS Mean		-42.15, 8.87
p-value		0.1857
Hedges' g (Zuranolone vs. Placebo)		-0.607
95% CI for Hedges' g		-1.5280, 0.3140

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	10.92 (2.995)	20.13 (2.967)
95% CI for the LS Mean	4.99, 16.85	14.26, 26.01
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.21 (4.216)
95% CI for the LS Mean		0.87, 17.56
p-value		0.0307
Hedges' g (Zuranolone vs. Placebo)		0.386
95% CI for Hedges' g		0.0345, 0.7366
Day 45		
n	60	63
LS Mean (SE)	7.96 (2.937)	22.45 (2.870)
95% CI for the LS Mean	2.14, 13.77	16.76, 28.13
Difference (Zuranolone - Placebo)		
LS Mean (SE)		14.49 (4.107)
95% CI for the LS Mean		6.36, 22.62
p-value		0.0006
Hedges' g (Zuranolone vs. Placebo)		0.633
95% CI for Hedges' g		0.2703, 0.9948

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.5.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	9.53 (3.037)	19.11 (2.910)
95% CI for the LS Mean	3.52, 15.54	13.35, 24.87
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.58 (4.207)
95% CI for the LS Mean		1.25, 17.91
p-value		0.0246
Hedges' g (Zuranolone vs. Placebo)		0.408
95% CI for Hedges' g		0.0510, 0.7658
Day 45		
n	55	64
LS Mean (SE)	9.01 (3.096)	23.00 (2.890)
95% CI for the LS Mean	2.88, 15.14	17.28, 28.72
Difference (Zuranolone - Placebo)		
LS Mean (SE)		13.99 (4.236)
95% CI for the LS Mean		5.60, 22.38
p-value		0.0013
Hedges' g (Zuranolone vs. Placebo)		0.603
95% CI for Hedges' g		0.2350, 0.9719

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Bodily Pain Subscale by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	21.78 (6.385)	19.80 (7.577)
95% CI for the LS Mean	8.48, 35.07	4.02, 35.57
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.98 (10.061)
95% CI for the LS Mean		-22.90, 18.94
p-value		0.8459
Hedges' g (Zuranolone vs. Placebo)		-0.079
95% CI for Hedges' g		-0.8905, 0.7331
Day 45		
n	14	9
LS Mean (SE)	16.85 (6.001)	8.67 (7.594)
95% CI for the LS Mean	4.29, 29.41	-7.18, 24.52
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-8.18 (9.874)
95% CI for the LS Mean		-28.78, 12.42
p-value		0.4174
Hedges' g (Zuranolone vs. Placebo)		-0.341
95% CI for Hedges' g		-1.1842, 0.5022

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

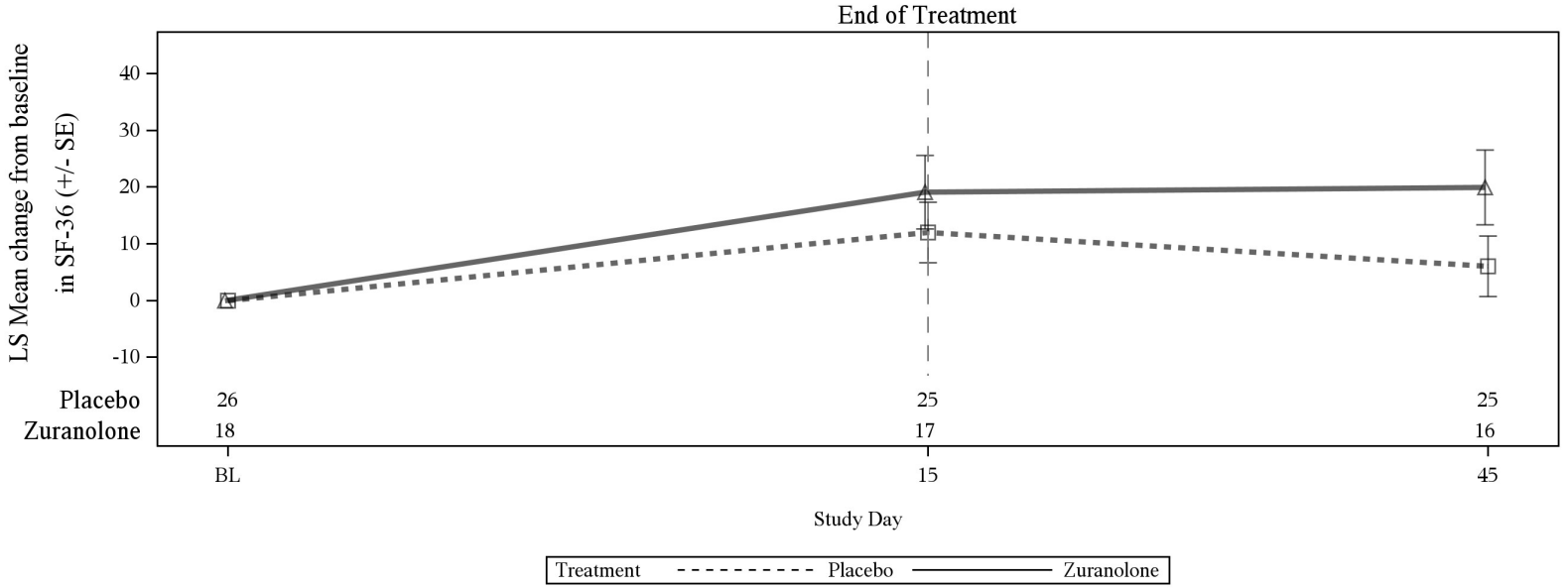
Source: biib125/v_a/germany_amnog/t-sf36-bp-mmrm-201-by.sas:t-sf36-bp-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.5.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

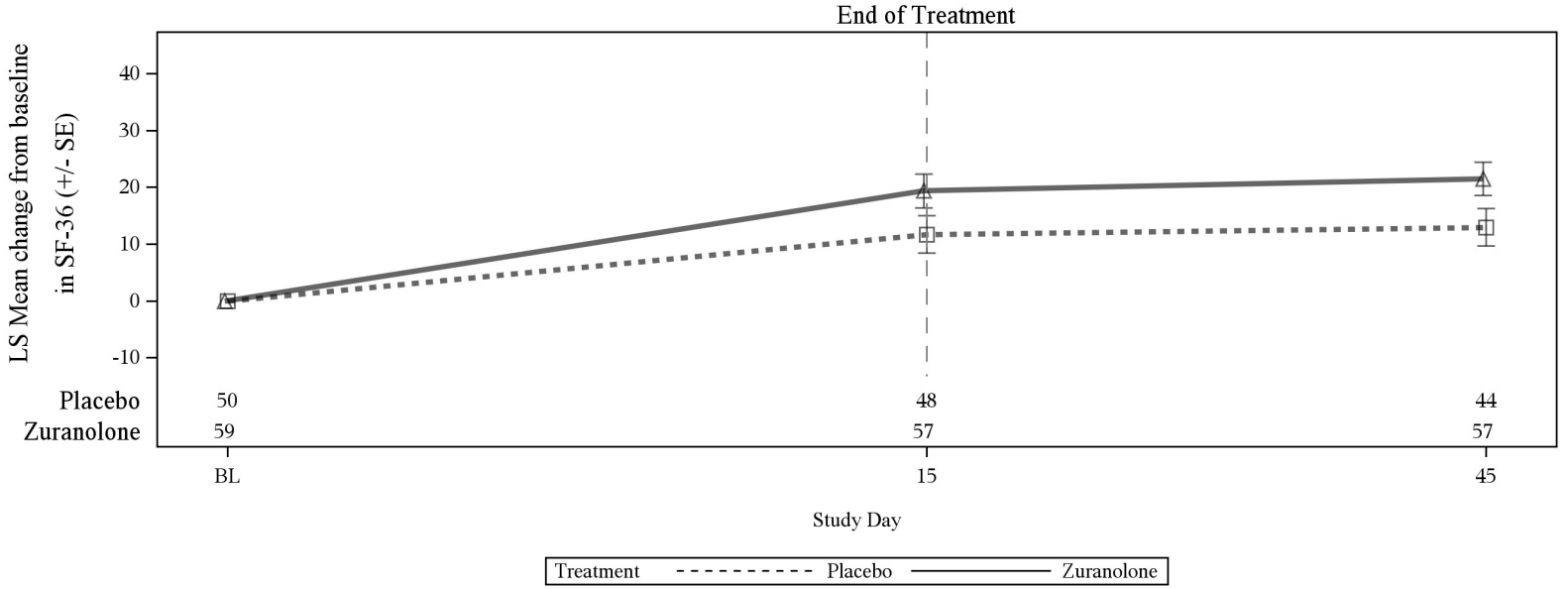
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

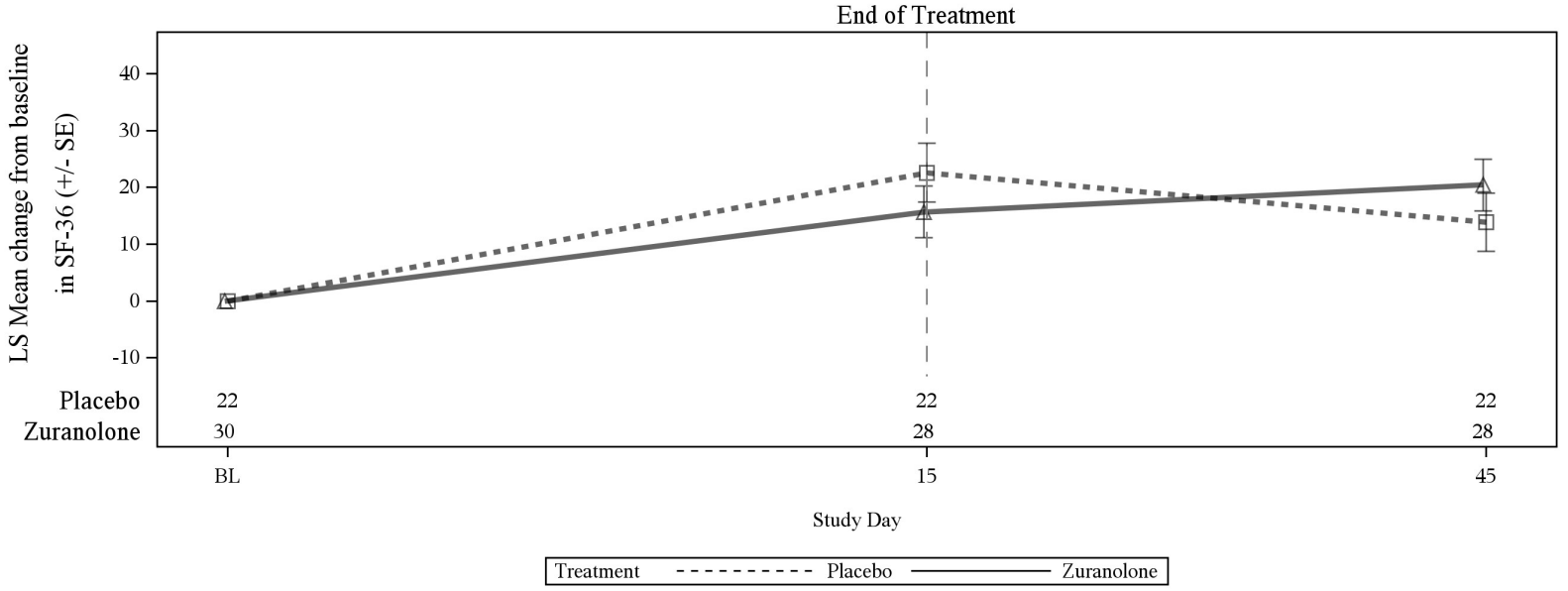
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

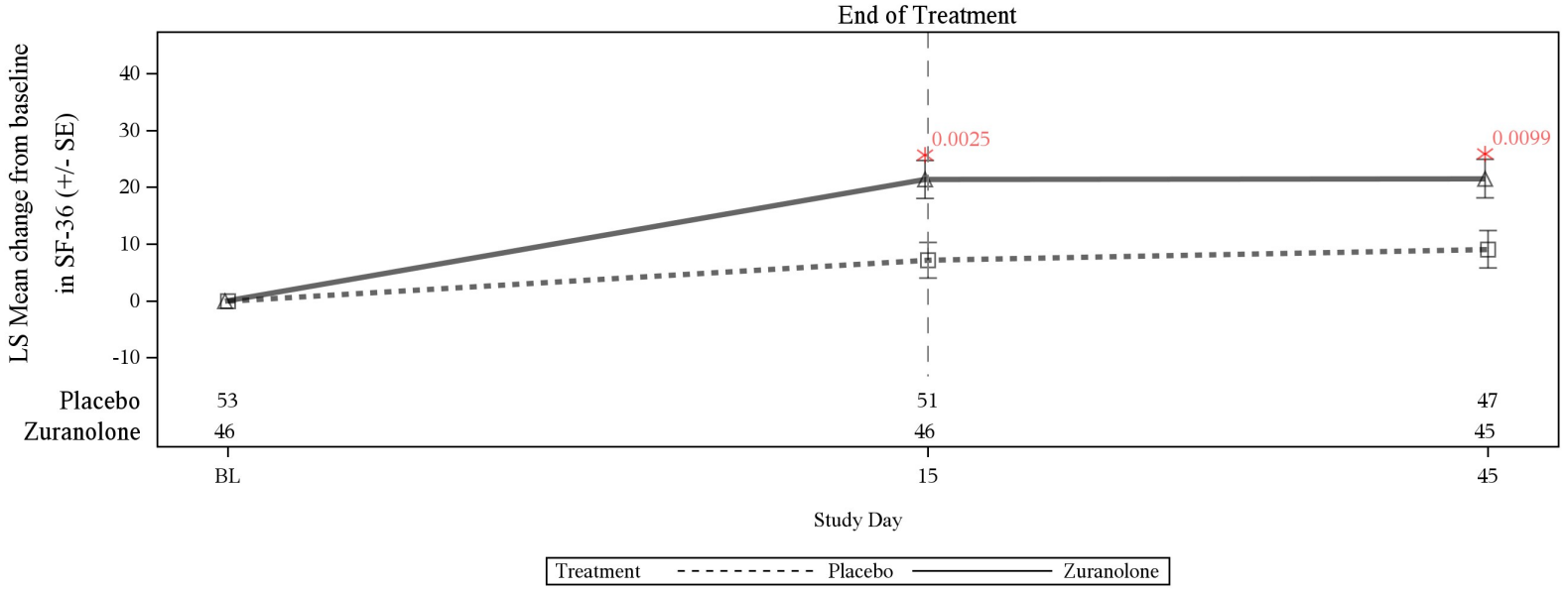
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Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

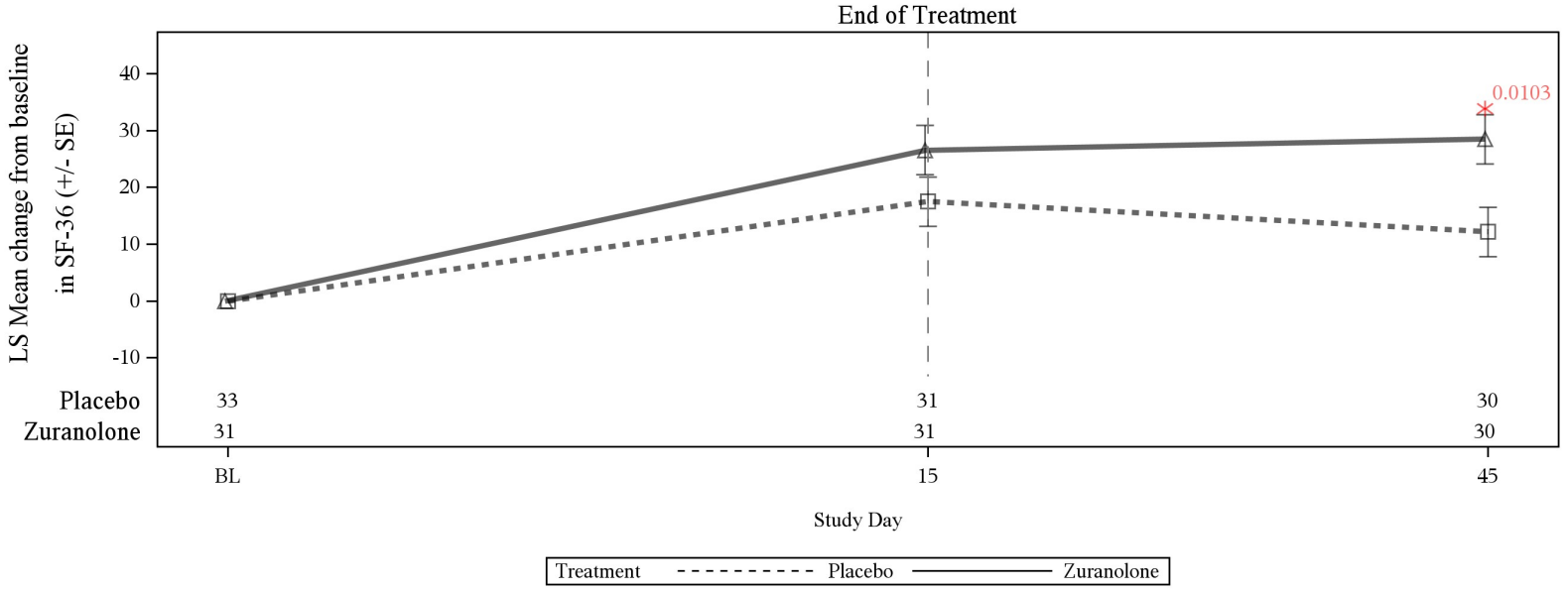
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

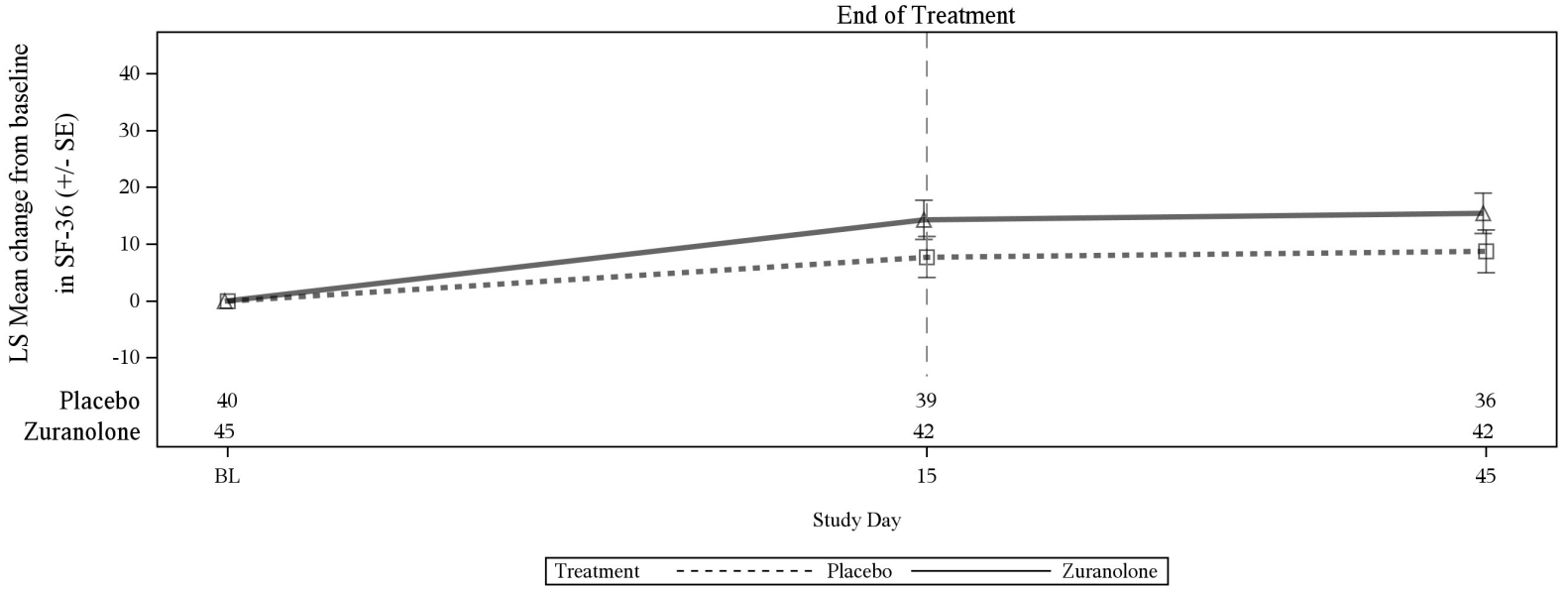
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

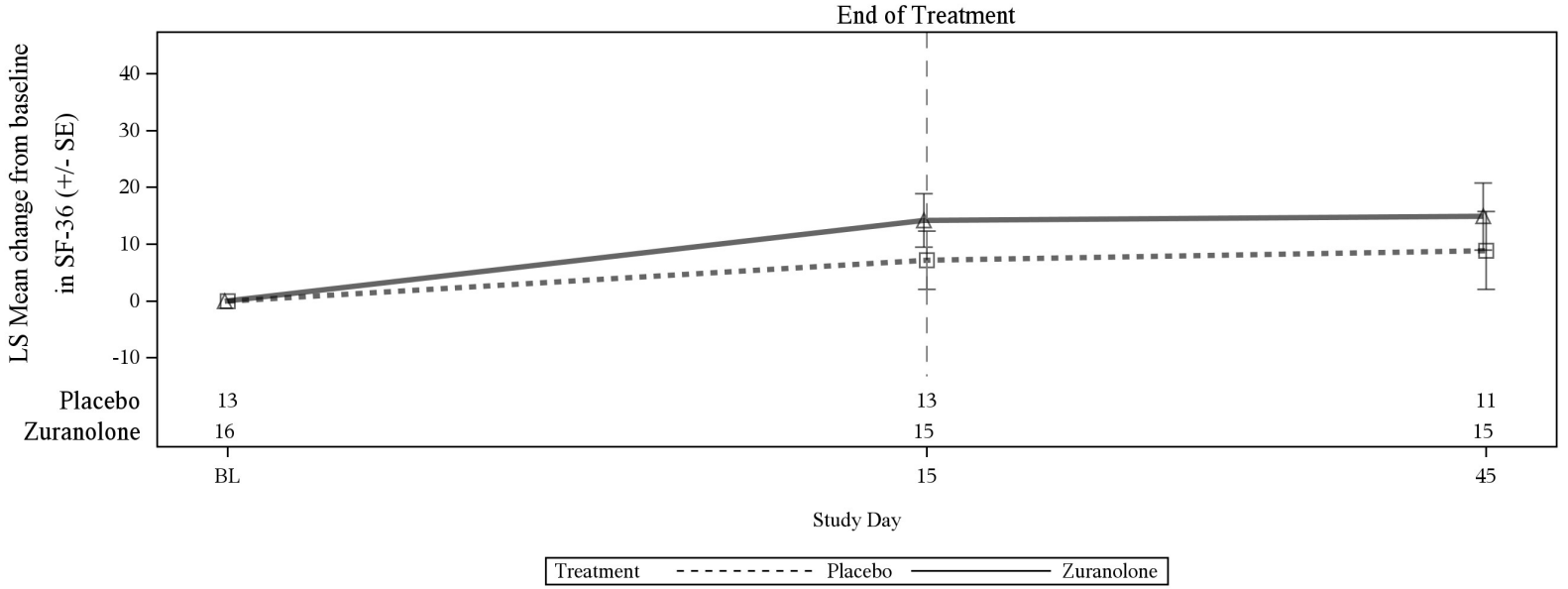
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

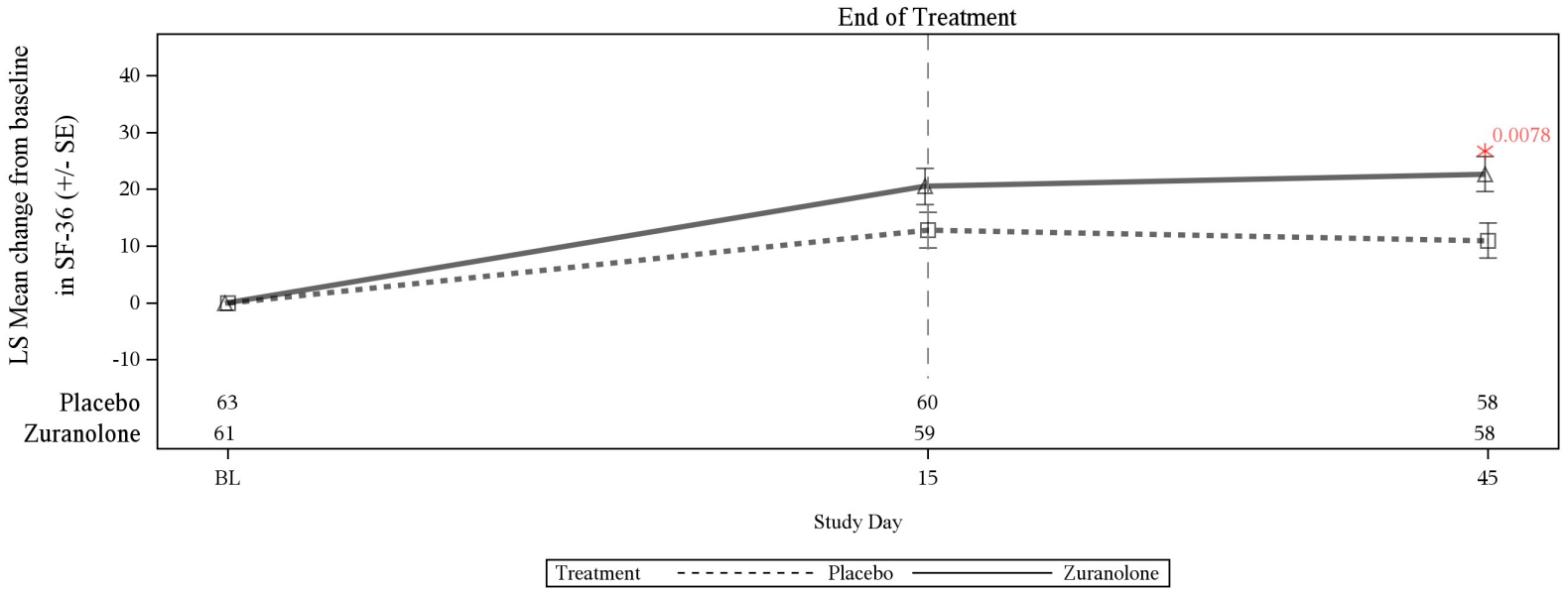
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

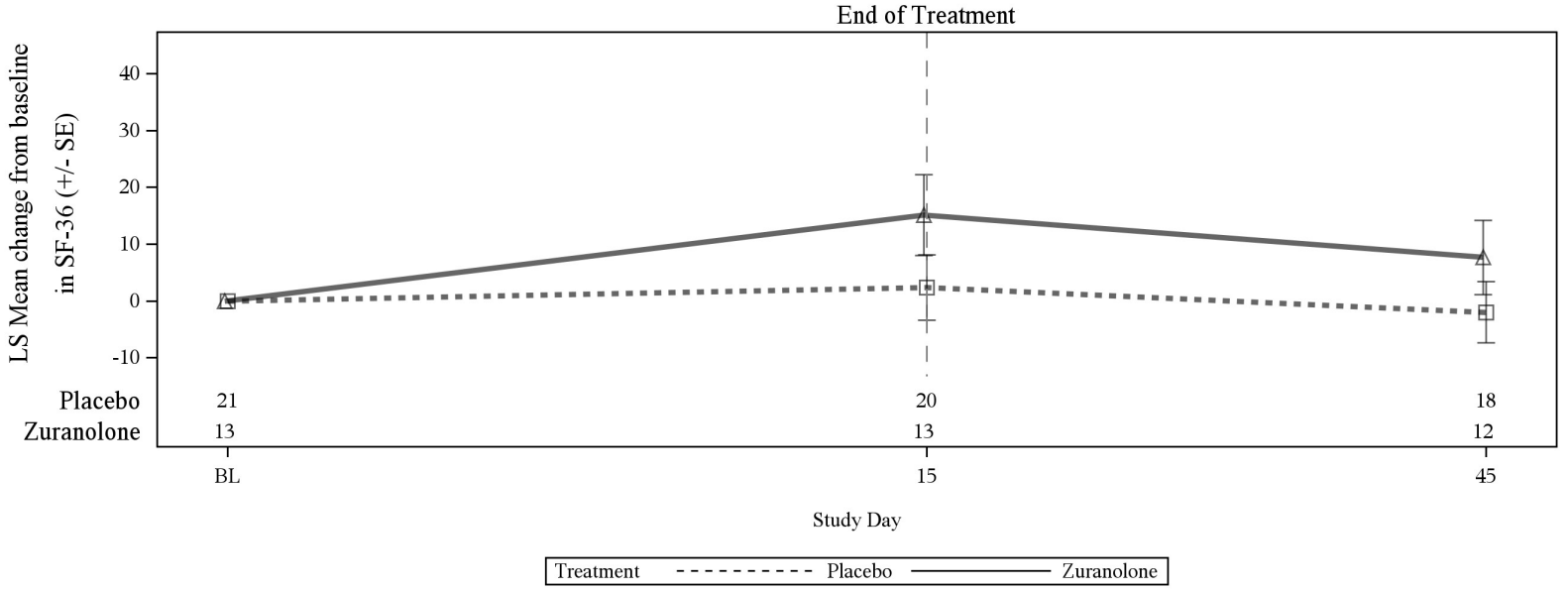
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

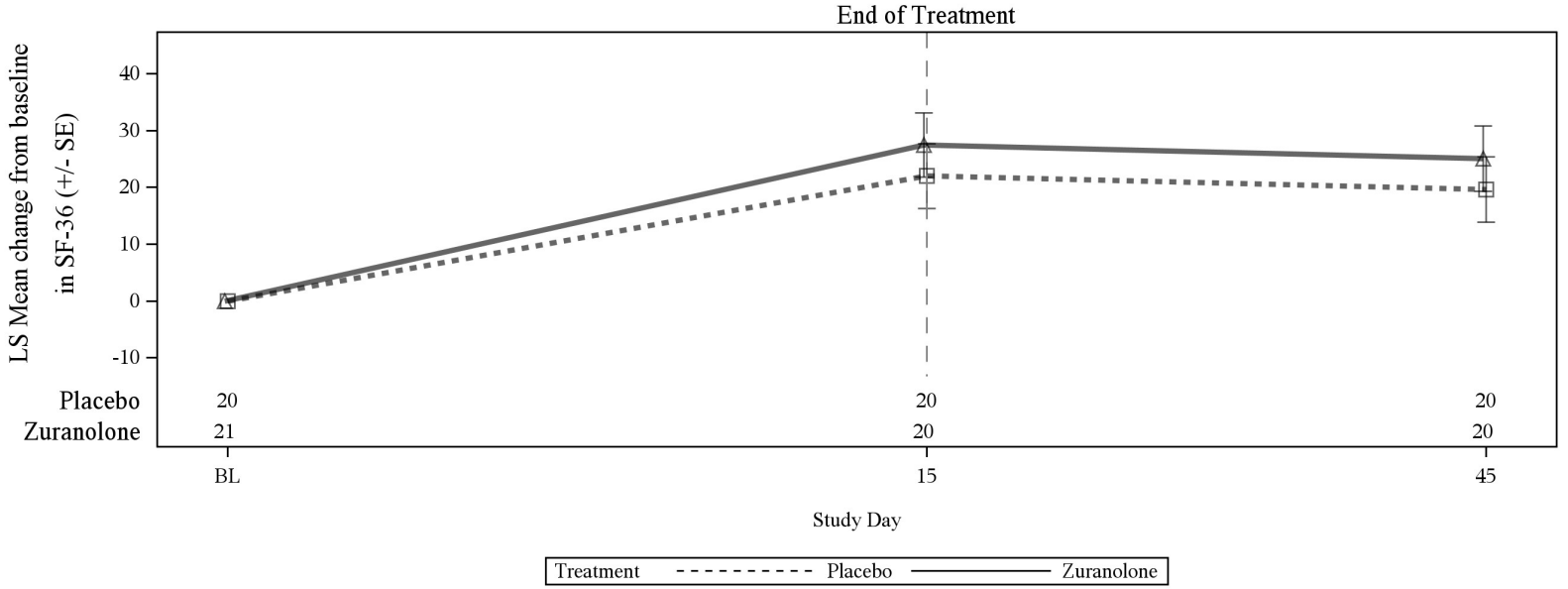
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

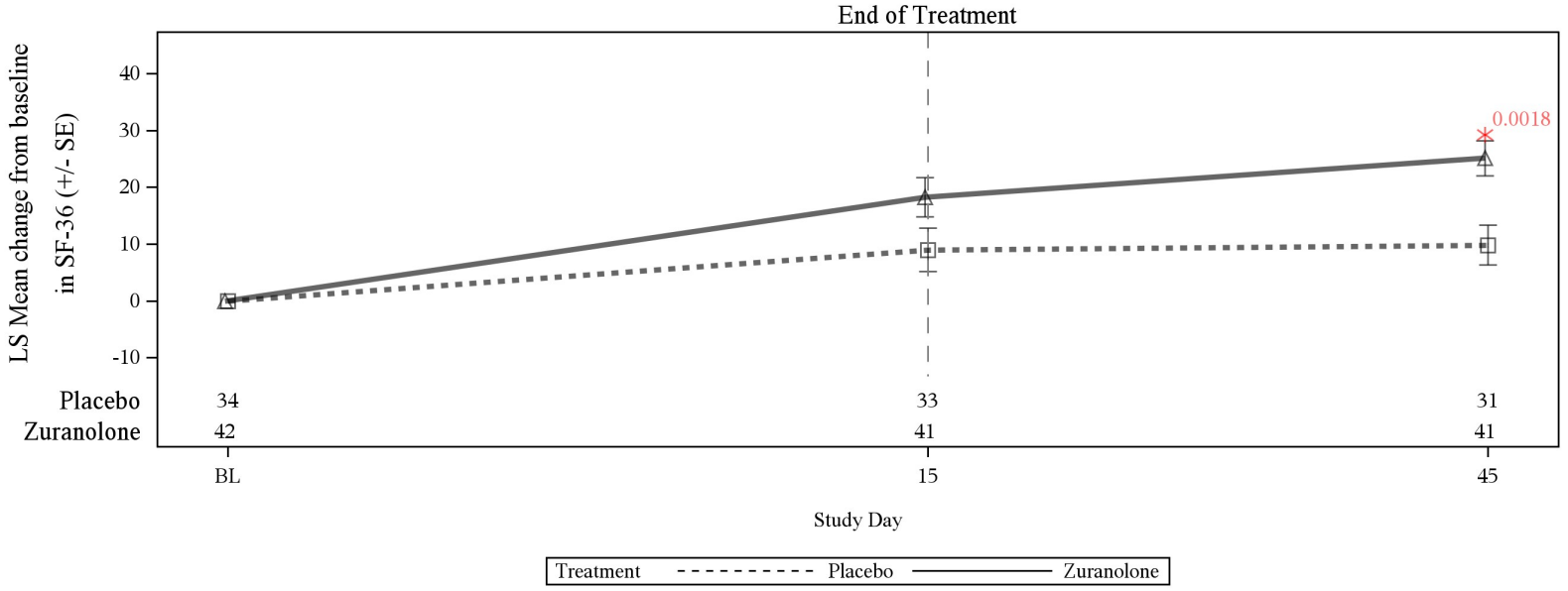
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

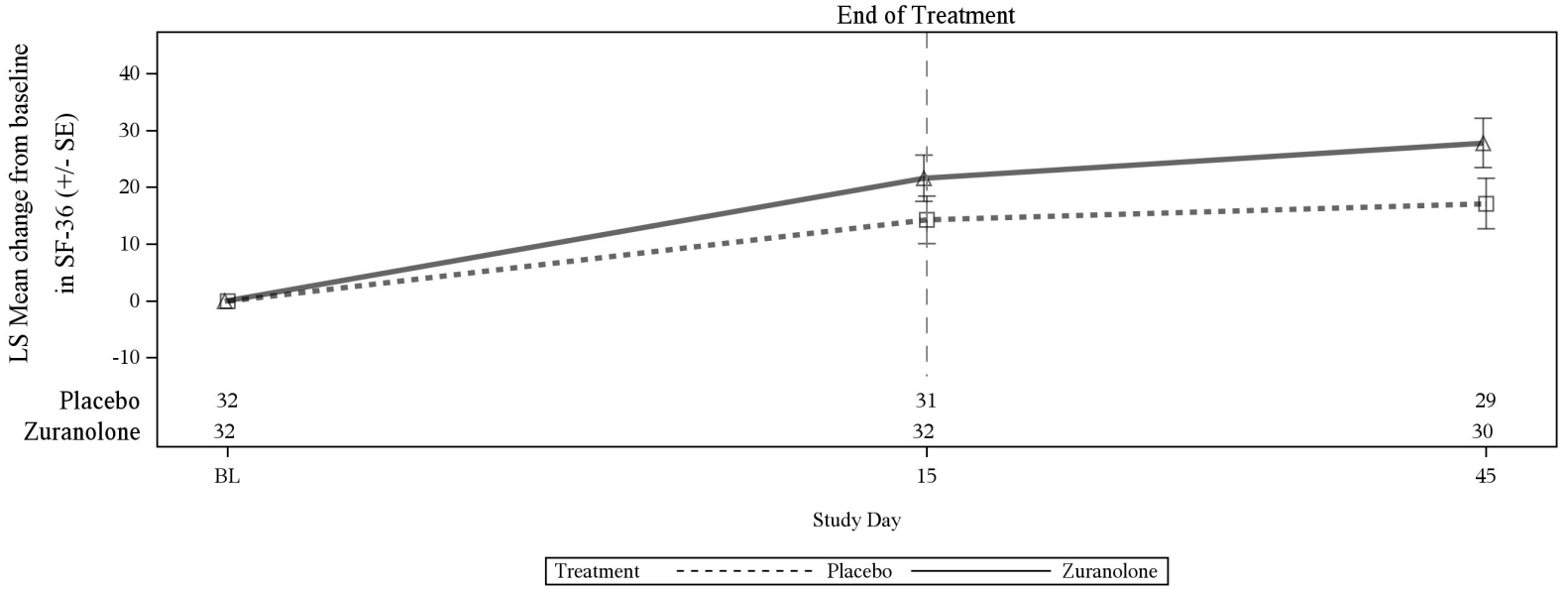
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

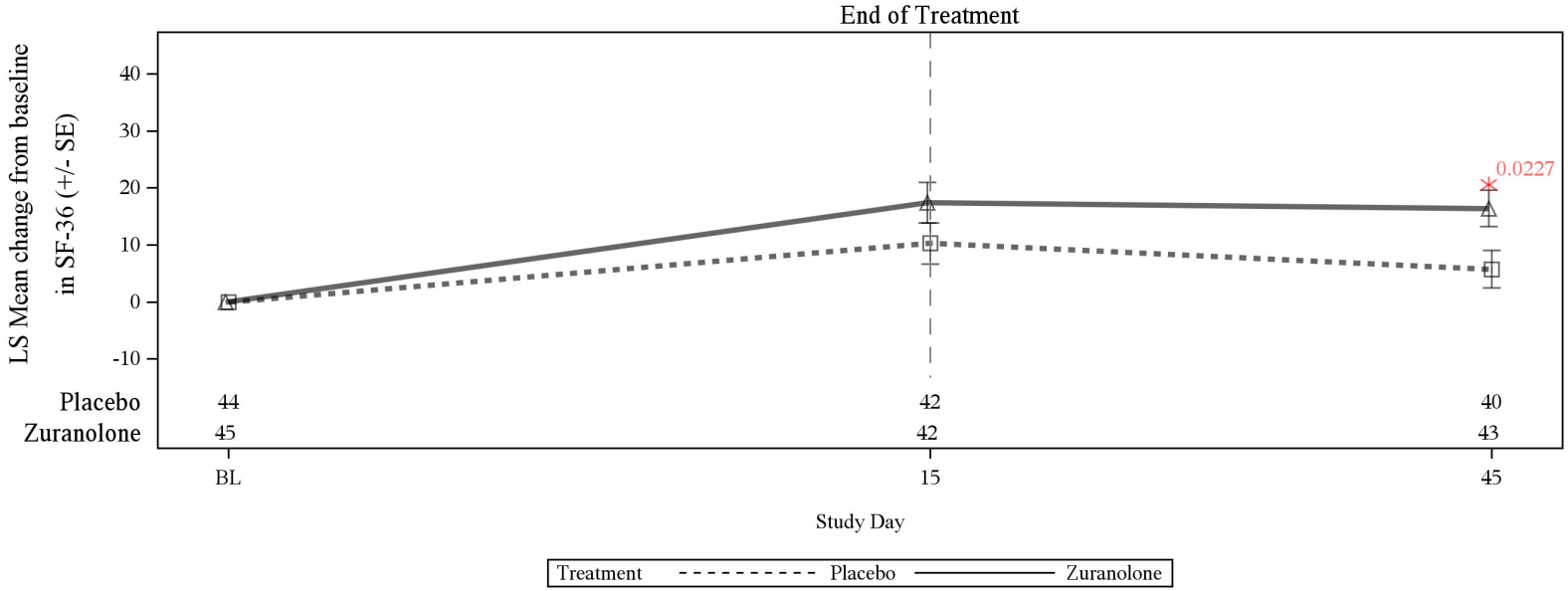
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

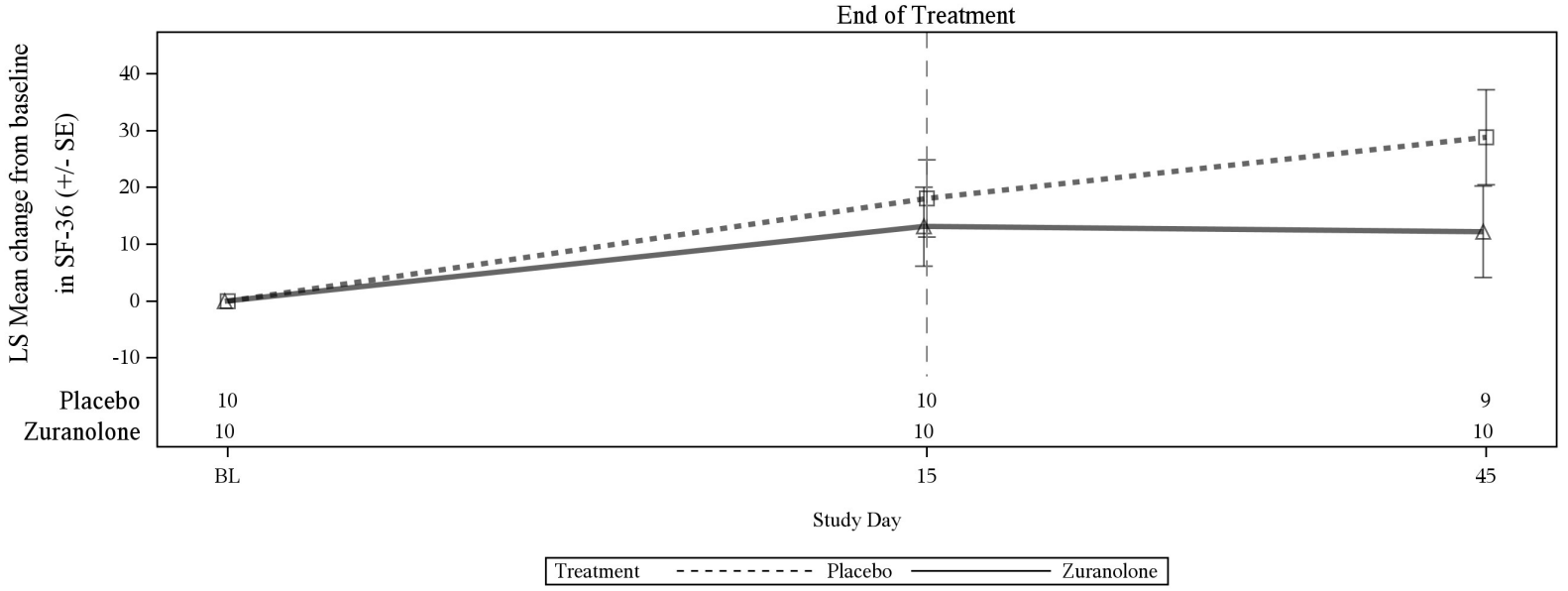
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

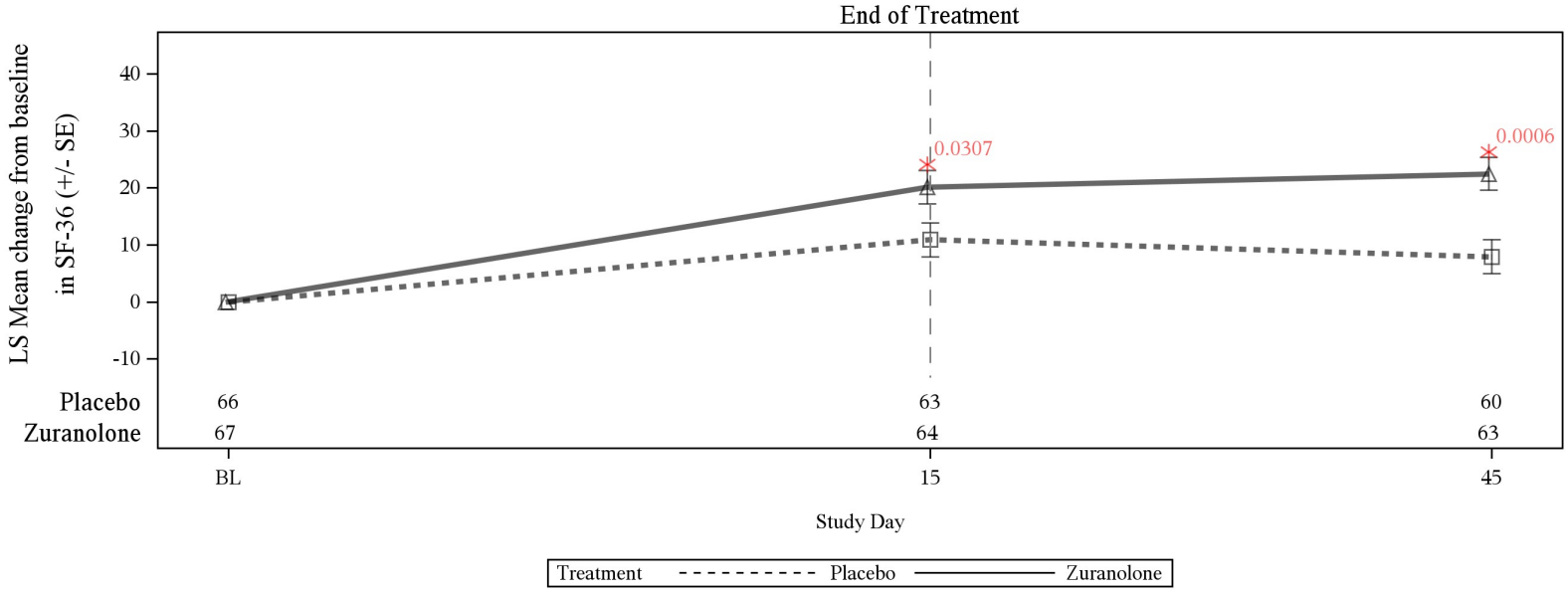
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

Page: 15 of 17

Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

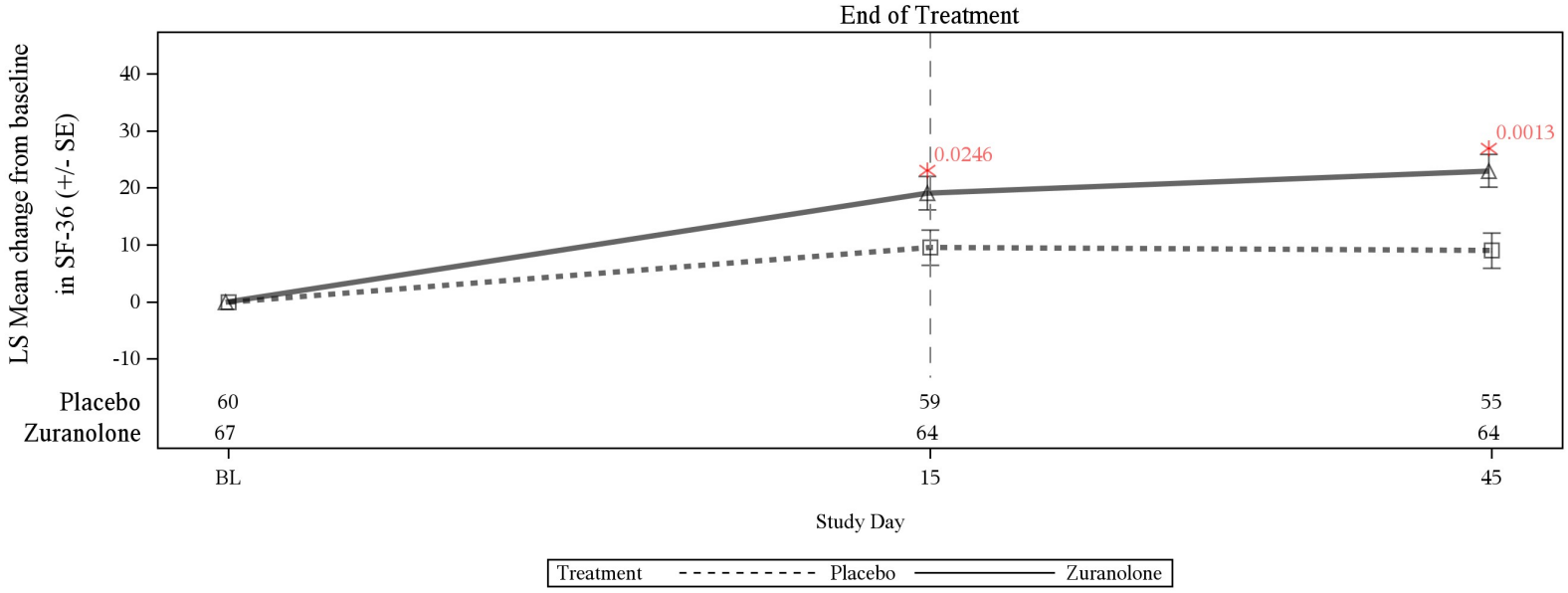
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

Page: 16 of 17

History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

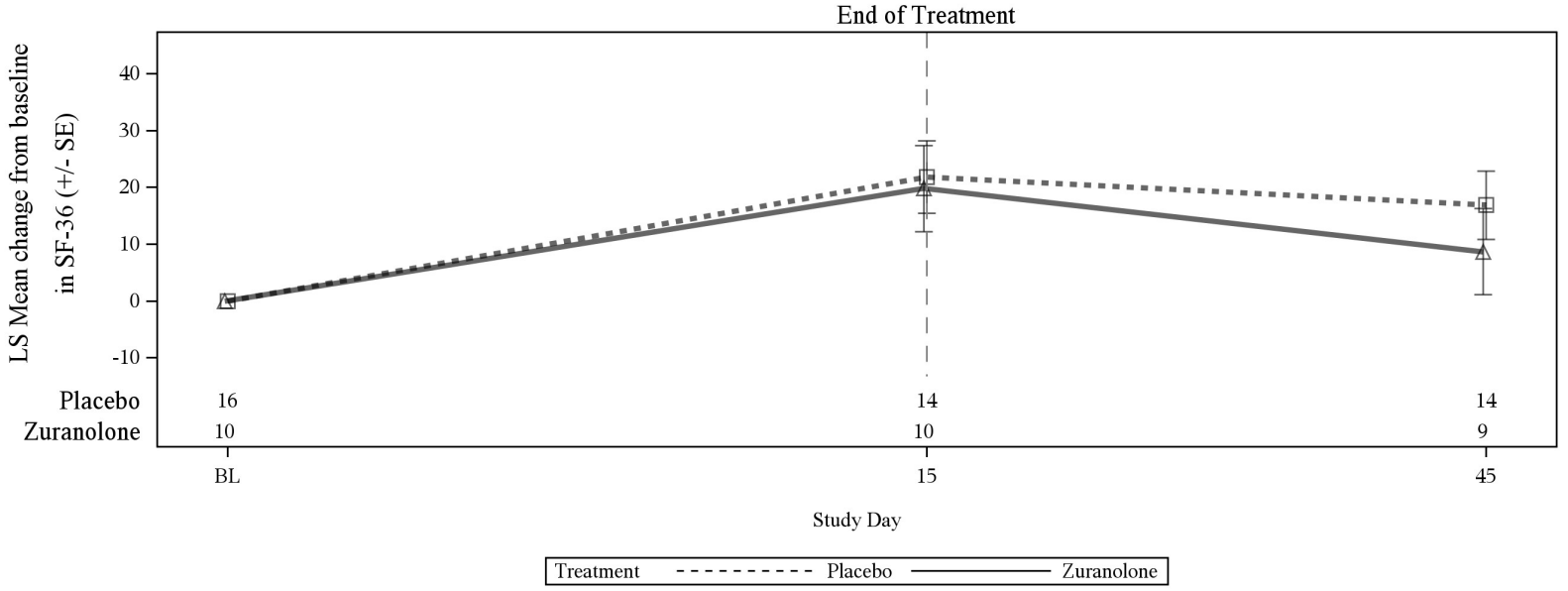
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Bodily Pain by Subgroup: 217-PPD-201B - ITT population

Page: 17 of 17

History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-bp-mmrm-201-by.sas:f-sf36-bp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

2.5.2 Ansprechen

2.5.2.1 Responder-Analysen

2.5.2.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with a response, n (%) [2]	32 (42.7)	40 (52.6)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.204
95% CI for the RR		(0.877, 1.652)
p-value for RR		0.2513
OR - Odds Ratio (Zuranolone vs. Placebo)		1.478
95% CI for the OR		(0.751, 2.905)
p-value for OR		0.2578
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.089
95% CI for the ARR		(-0.045, 0.224)
p-value for ARR		0.1934

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-ovr.sas:t-sf36-bp-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	29 (38.7)	44 (57.9)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.461
95% CI for the RR		(1.051, 2.032)
p-value for RR		0.0243
OR - Odds Ratio (Zuranolone vs. Placebo)		2.266
95% CI for the OR		(1.123, 4.572)
p-value for OR		0.0224
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.173
95% CI for the ARR		(0.036, 0.309)
p-value for ARR		0.0130

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-ovr.sas:t-sf36-bp-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.5.2.1 .2 Subgruppen

2.5.2.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	32 (42.7)	40 (52.6)	
Number of subjects with response at Day 45, n (%)	29 (38.7)	44 (57.9)	
Age Group (years)			0.4810
Day 15			
18 - 24, n / N (%)	10/25 (40.0)	10/17 (58.8)	
25 - 45, n / N (%)	22/50 (44.0)	30/59 (50.8)	
Day 45			
18 - 24, n / N (%)	8/25 (32.0)	11/17 (64.7)	
25 - 45, n / N (%)	21/50 (42.0)	33/59 (55.9)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-int.sas:t-sf36-bp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.0435
Day 15			
<28, n / N (%)	14/22 (63.6)	14/30 (46.7)	
>=28, n / N (%)	18/53 (34.0)	26/46 (56.5)	
Day 45			
<28, n / N (%)	10/22 (45.5)	16/30 (53.3)	
>=28, n / N (%)	19/53 (35.8)	28/46 (60.9)	
Race Group (Black or African American, White)			0.3673
Day 15			
Black or African American, n / N (%)	15/32 (46.9)	19/31 (61.3)	
White, n / N (%)	16/40 (40.0)	21/44 (47.7)	
Day 45			
Black or African American, n / N (%)	14/32 (43.8)	21/31 (67.7)	
White, n / N (%)	13/40 (32.5)	22/44 (50.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-int.sas:t-sf36-bp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.9229
Day 15			
Yes, n / N (%)	5/13 (38.5)	8/16 (50.0)	
No, n / N (%)	27/62 (43.5)	32/60 (53.3)	
Day 45			
Yes, n / N (%)	4/13 (30.8)	9/16 (56.3)	
No, n / N (%)	25/62 (40.3)	35/60 (58.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-int.sas:t-sf36-bp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.2272(a) 0.4188(b) 0.4956(c)
Day 15			
<=24.9, n / N (%)	6/21 (28.6)	7/13 (53.8)	
25-29.9, n / N (%)	10/20 (50.0)	11/21 (52.4)	
>=30, n / N (%)	16/34 (47.1)	22/42 (52.4)	
Day 45			
<=24.9, n / N (%)	4/21 (19.0)	5/13 (38.5)	
25-29.9, n / N (%)	12/20 (60.0)	11/21 (52.4)	
>=30, n / N (%)	13/34 (38.2)	28/42 (66.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-int.sas:t-sf36-bp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.9132
Day 15			
3rd Trimester, n / N (%)	13/32 (40.6)	18/32 (56.3)	
Postpartum, n / N (%)	19/43 (44.2)	22/44 (50.0)	
Day 45			
3rd Trimester, n / N (%)	14/32 (43.8)	20/32 (62.5)	
Postpartum, n / N (%)	15/43 (34.9)	24/44 (54.5)	
Family History of PPD			0.0871
Day 15			
Yes, n / N (%)	5/10 (50.0)	5/10 (50.0)	
No/Unknown, n / N (%)	27/65 (41.5)	35/66 (53.0)	
Day 45			
Yes, n / N (%)	7/10 (70.0)	5/10 (50.0)	
No/Unknown, n / N (%)	22/65 (33.8)	39/66 (59.1)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-int.sas:t-sf36-bp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.7891
Day 15			
1st Episode, n / N (%)	23/59 (39.0)	32/66 (48.5)	
Recurrent Episode, n / N (%)	9/16 (56.3)	8/10 (80.0)	
Day 45			
1st Episode, n / N (%)	23/59 (39.0)	40/66 (60.6)	
Recurrent Episode, n / N (%)	6/16 (37.5)	4/10 (40.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	4/8 (50.0)	7/10 (70.0)	
>=20, n / N (%)	28/67 (41.8)	33/66 (50.0)	
Day 45			
<20, n / N (%)	4/8 (50.0)	5/10 (50.0)	
>=20, n / N (%)	25/67 (37.3)	39/66 (59.1)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-int.sas:t-sf36-bp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

2.5.2.1 .2 .2 Subgruppenanalysen

2.5.2.1 .2 .2 .1 Alter

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 15		
Number of subjects with a response, n (%) [2]	10 (40.0)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.299
95% CI for the RR		(0.718, 2.349)
p-value for RR		0.3868
Day 45		
Number of subjects with a response, n (%) [2]	8 (32.0)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.786
95% CI for the RR		(0.933, 3.420)
p-value for RR		0.0801

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 15		
Number of subjects with a response, n (%) [2]	22 (44.0)	30 (50.8)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.171
95% CI for the RR		(0.808, 1.695)
p-value for RR		0.4050
Day 45		
Number of subjects with a response, n (%) [2]	21 (42.0)	33 (55.9)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.349
95% CI for the RR		(0.920, 1.977)
p-value for RR		0.1252

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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2.5.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 15		
Number of subjects with a response, n (%) [2]	14 (63.6)	14 (46.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.725
95% CI for the RR		(0.449, 1.172)
p-value for RR		0.1898
Day 45		
Number of subjects with a response, n (%) [2]	10 (45.5)	16 (53.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.160
95% CI for the RR		(0.667, 2.019)
p-value for RR		0.5984

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 15		
Number of subjects with a response, n (%) [2]	18 (34.0)	26 (56.5)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.618
95% CI for the RR		(1.067, 2.453)
p-value for RR		0.0235
Day 45		
Number of subjects with a response, n (%) [2]	19 (35.8)	28 (60.9)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.651
95% CI for the RR		(1.098, 2.482)
p-value for RR		0.0160

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.5.2.1 .2 .2 .3 Abstammung

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 15		
Number of subjects with a response, n (%) [2]	15 (46.9)	19 (61.3)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.412
95% CI for the RR		(0.950, 2.099)
p-value for RR		0.0877
Day 45		
Number of subjects with a response, n (%) [2]	14 (43.8)	21 (67.7)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.673
95% CI for the RR		(1.087, 2.574)
p-value for RR		0.0193

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 15		
Number of subjects with a response, n (%) [2]	16 (40.0)	21 (47.7)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.045
95% CI for the RR		(0.637, 1.714)
p-value for RR		0.8618
Day 45		
Number of subjects with a response, n (%) [2]	13 (32.5)	22 (50.0)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.347
95% CI for the RR		(0.790, 2.298)
p-value for RR		0.2738

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.5.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 15		
Number of subjects with a response, n (%) [2]	5 (38.5)	8 (50.0)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.159
95% CI for the RR		(0.507, 2.648)
p-value for RR		0.7260
Day 45		
Number of subjects with a response, n (%) [2]	4 (30.8)	9 (56.3)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.630
95% CI for the RR		(0.620, 4.283)
p-value for RR		0.3215

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 15		
Number of subjects with a response, n (%) [2]	27 (43.5)	32 (53.3)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.213
95% CI for the RR		(0.858, 1.714)
p-value for RR		0.2737
Day 45		
Number of subjects with a response, n (%) [2]	25 (40.3)	35 (58.3)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.433
95% CI for the RR		(1.008, 2.037)
p-value for RR		0.0450

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.5.2.1 .2 .2 .5 BMI

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 15		
Number of subjects with a response, n (%) [2]	6 (28.6)	7 (53.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.903
95% CI for the RR		(0.904, 4.005)
p-value for RR		0.0900
Day 45		
Number of subjects with a response, n (%) [2]	4 (19.0)	5 (38.5)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.039
95% CI for the RR		(0.688, 6.048)
p-value for RR		0.1990

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 15		
Number of subjects with a response, n (%) [2]	10 (50.0)	11 (52.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.190
95% CI for the RR		(0.692, 2.047)
p-value for RR		0.5292
Day 45		
Number of subjects with a response, n (%) [2]	12 (60.0)	11 (52.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.992
95% CI for the RR		(0.596, 1.652)
p-value for RR		0.9748

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 15		
Number of subjects with a response, n (%) [2]	16 (47.1)	22 (52.4)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.075
95% CI for the RR		(0.687, 1.681)
p-value for RR		0.7521
Day 45		
Number of subjects with a response, n (%) [2]	13 (38.2)	28 (66.7)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.684
95% CI for the RR		(1.053, 2.691)
p-value for RR		0.0295

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.5.2.1 .2 .2 .6 Beginn der PPD

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 15		
Number of subjects with a response, n (%) [2]	13 (40.6)	18 (56.3)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.314
95% CI for the RR		(0.859, 2.011)
p-value for RR		0.2081
Day 45		
Number of subjects with a response, n (%) [2]	14 (43.8)	20 (62.5)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.356
95% CI for the RR		(0.867, 2.120)
p-value for RR		0.1819

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 15		
Number of subjects with a response, n (%) [2]	19 (44.2)	22 (50.0)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.131
95% CI for the RR		(0.728, 1.758)
p-value for RR		0.5843
Day 45		
Number of subjects with a response, n (%) [2]	15 (34.9)	24 (54.5)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.563
95% CI for the RR		(0.974, 2.507)
p-value for RR		0.0641

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.5.2.1 .2 .2 .7 PPD in der Familie

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 15		
Number of subjects with a response, n (%) [2]	5 (50.0)	5 (50.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.117
95% CI for the RR		(0.483, 2.586)
p-value for RR		0.7956
Day 45		
Number of subjects with a response, n (%) [2]	7 (70.0)	5 (50.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.798
95% CI for the RR		(0.407, 1.565)
p-value for RR		0.5116

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 15		
Number of subjects with a response, n (%) [2]	27 (41.5)	35 (53.0)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.259
95% CI for the RR		(0.894, 1.772)
p-value for RR		0.1872
Day 45		
Number of subjects with a response, n (%) [2]	22 (33.8)	39 (59.1)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.721
95% CI for the RR		(1.184, 2.503)
p-value for RR		0.0045

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.5.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 15		
Number of subjects with a response, n (%) [2]	23 (39.0)	32 (48.5)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.217
95% CI for the RR		(0.828, 1.790)
p-value for RR		0.3178
Day 45		
Number of subjects with a response, n (%) [2]	23 (39.0)	40 (60.6)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.521
95% CI for the RR		(1.064, 2.177)
p-value for RR		0.0216

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 15		
Number of subjects with a response, n (%) [2]	9 (56.3)	8 (80.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.175
95% CI for the RR		(0.684, 2.017)
p-value for RR		0.5591
Day 45		
Number of subjects with a response, n (%) [2]	6 (37.5)	4 (40.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.881
95% CI for the RR		(0.351, 2.209)
p-value for RR		0.7873

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

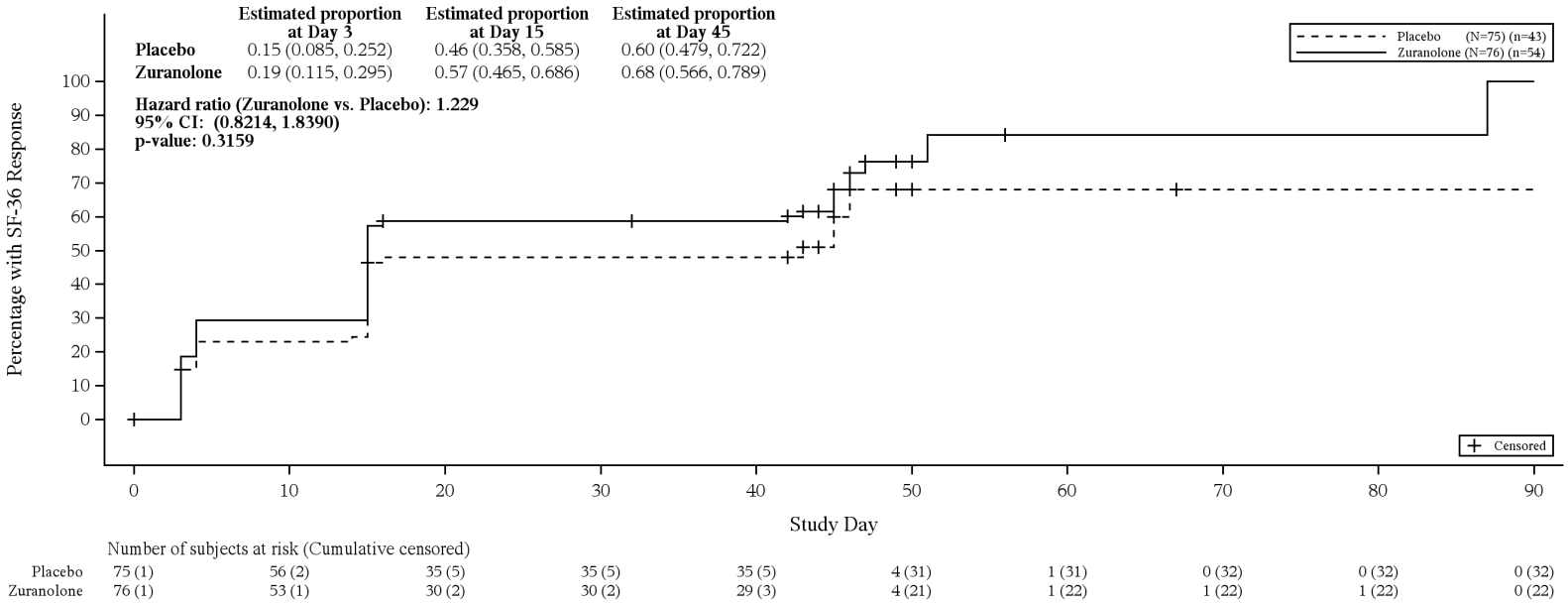
Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-201-by.sas:t-sf36-bp-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.5.2.2 TTE-Analysen

2.5.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-ovr.sas:f-sf36-bp-resp15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	43 (57.3)	54 (71.1)
Time to first SF-36 Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	43.0 (15.0 , 46.0)	15.0 (15.0 , 43.0)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	47.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.229
95% CI for the HR		(0.8214 , 1.8390)
p-value for the HR		0.3159

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-ovr.sas:t-sf36-bp-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.5.2.2 .2 Subgruppen

2.5.2.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	43 (57.3)	54 (71.1)	
Age Group (years)			
18 - 24, n / N (%)	16/25 (64.0)	15/17 (88.2)	0.8354
25 - 45, n / N (%)	27/50 (54.0)	39/59 (66.1)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	16/22 (72.7)	21/30 (70.0)	0.4413
>=28, n / N (%)	27/53 (50.9)	33/46 (71.7)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	20/32 (62.5)	26/31 (83.9)	0.5332
White, n / N (%)	21/40 (52.5)	27/44 (61.4)	
Antidepressant Use at Baseline			
Yes, n / N (%)	8/13 (61.5)	10/16 (62.5)	0.8762
No, n / N (%)	35/62 (56.5)	44/60 (73.3)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-int.sas:t-sf36-bp-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	8/21 (38.1)	8/13 (61.5)	0.0746(a)
25-29.9, n / N (%)	14/20 (70.0)	13/21 (61.9)	0.2058(b)
>=30, n / N (%)	21/34 (61.8)	33/42 (78.6)	0.4139(c)
Onset of PPD			
3rd Trimester, n / N (%)	19/32 (59.4)	26/32 (81.3)	0.8995
Postpartum, n / N (%)	24/43 (55.8)	28/44 (63.6)	
Family History of PPD			
Yes, n / N (%)	9/10 (90.0)	6/10 (60.0)	0.1032
No/Unknown, n / N (%)	34/65 (52.3)	48/66 (72.7)	
History of PPD			
1st Episode, n / N (%)	33/59 (55.9)	45/66 (68.2)	0.9011
Recurrent Episode, n / N (%)	10/16 (62.5)	9/10 (90.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	5/8 (62.5)	8/10 (80.0)	NA
>=20, n / N (%)	38/67 (56.7)	46/66 (69.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-int.sas:t-sf36-bp-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.5.2.2 .2 .2 Subgruppenanalysen

2.5.2.2 .2 .2 .1 Alter

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	16 (64.0)	15 (88.2)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	43.0 (15.0 , 46.0)	15.0 (3.0 , 42.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	42.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.389
95% CI for the HR		(0.6701 , 2.8782)
p-value for the HR		0.3771

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	27 (54.0)	39 (66.1)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	14.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	43.0 (15.0, NE)	15.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	47.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.216
95% CI for the HR		(0.7438 , 1.9874)
p-value for the HR		0.4358

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.5.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	16 (72.7)	21 (70.0)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 46.0)	15.0 (15.0 , 46.0)
75th percentile - Q3 (95% CI)	46.0 (15.0, NE)	47.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.998
95% CI for the HR		(0.5187 , 1.9221)
p-value for the HR		0.9963

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	27 (50.9)	33 (71.7)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	15.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	51.0 (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.390
95% CI for the HR		(0.8309 , 2.3252)
p-value for the HR		0.2097

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.5.2.2 .2 .2 .3 Abstammung

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	20 (62.5)	26 (83.9)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (4.0 , 46.0)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	46.0 (45.0, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.365
95% CI for the HR		(0.7534 , 2.4719)
p-value for the HR		0.3049

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	21 (52.5)	27 (61.4)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	43.0 (15.0, NE)	16.0 (15.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	51.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.096
95% CI for the HR		(0.6127 , 1.9607)
p-value for the HR		0.7572

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.5.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	8 (61.5)	10 (62.5)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 43.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	43.0 (15.0, NE)	15.0 (4.0, NE)
75th percentile - Q3 (95% CI)	NE (16.0, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.167
95% CI for the HR		(0.4579 , 2.9727)
p-value for the HR		0.7466

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	35 (56.5)	44 (73.3)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	14.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	43.0 (15.0 , 46.0)	15.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	47.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.240
95% CI for the HR		(0.7931 , 1.9393)
p-value for the HR		0.3454

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.5.2.2 .2 .2 .5 BMI

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	8 (38.1)	8 (61.5)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0, NE)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	NE (15.0, NE)	15.0 (3.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.444
95% CI for the HR		(0.8706 , 6.8596)
p-value for the HR		0.0897

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	14 (70.0)	13 (61.9)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (3.0 , 45.0)	15.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	NE (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.904
95% CI for the HR		(0.4138 , 1.9734)
p-value for the HR		0.7993

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	21 (61.8)	33 (78.6)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	16.0 (15.0 , 46.0)	15.0 (4.0 , 45.0)
75th percentile - Q3 (95% CI)	46.0 (45.0, NE)	46.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.188
95% CI for the HR		(0.6762 , 2.0870)
p-value for the HR		0.5491

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.5.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	19 (59.4)	26 (81.3)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	3.5 (3.0 , 4.0)
50th percentile - median (95% CI)	45.0 (4.0 , 46.0)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	46.0 (45.0, NE)	45.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.229
95% CI for the HR		(0.6713 , 2.2503)
p-value for the HR		0.5037

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	24 (55.8)	28 (63.6)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	43.0 (15.0, NE)	16.0 (15.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	46.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.198
95% CI for the HR		(0.6926 , 2.0716)
p-value for the HR		0.5183

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.5.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	9 (90.0)	6 (60.0)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 16.0)	15.0 (3.0 , 42.0)
50th percentile - median (95% CI)	15.5 (3.0, NE)	28.5 (3.0, NE)
75th percentile - Q3 (95% CI)	46.0 (15.0, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.636
95% CI for the HR		(0.1944 , 2.0782)
p-value for the HR		0.4535

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	34 (52.3)	48 (72.7)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	15.0 (15.0 , 43.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	47.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.425
95% CI for the HR		(0.9161 , 2.2179)
p-value for the HR		0.1161

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.5.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	33 (55.9)	45 (68.2)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (15.0 , 46.0)	15.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	51.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.249
95% CI for the HR		(0.7946 , 1.9632)
p-value for the HR		0.3354

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	10 (62.5)	9 (90.0)
Time to first Bodily Pain Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (3.0, NE)	15.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	15.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.202
95% CI for the HR		(0.4510 , 3.2055)
p-value for the HR		0.7127

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

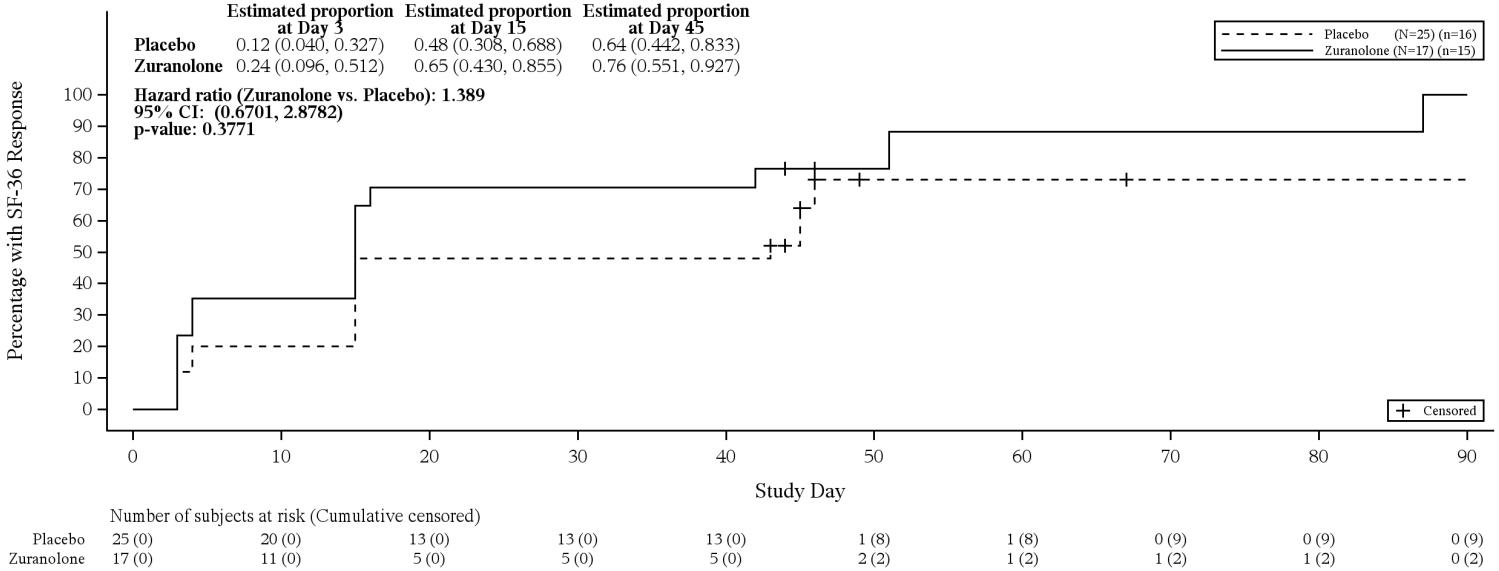
Source: biib125/v_a/germany_amnog/t-sf36-bp-resp15-tte-201-by.sas:t-sf36-bp-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.5.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

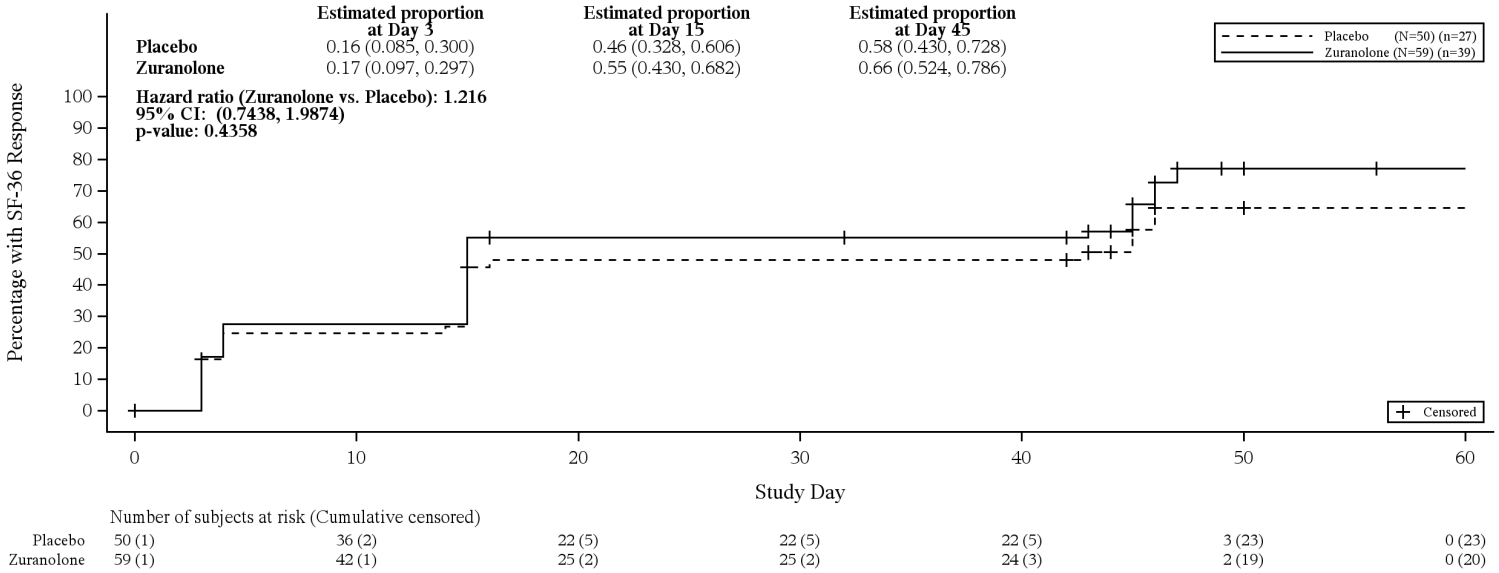
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-by.sas:f-sf36-bp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

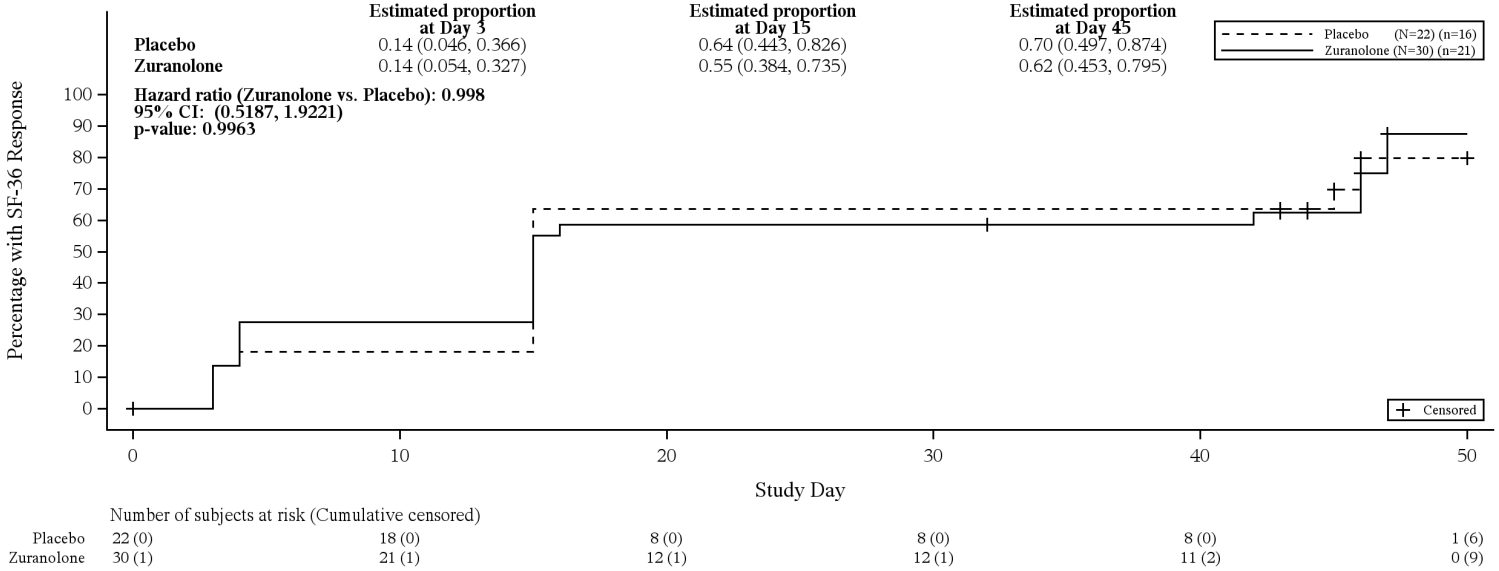
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Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-by.sas:f-sf36-bp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

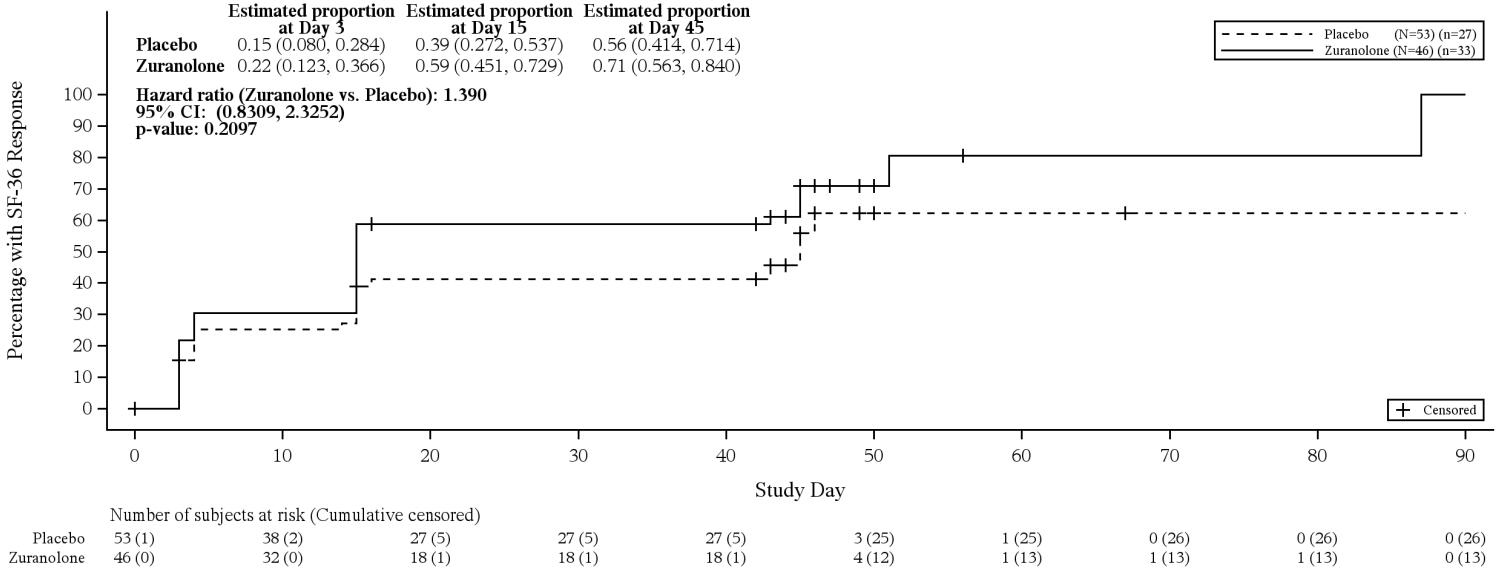
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-by.sas:f-sf36-bp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

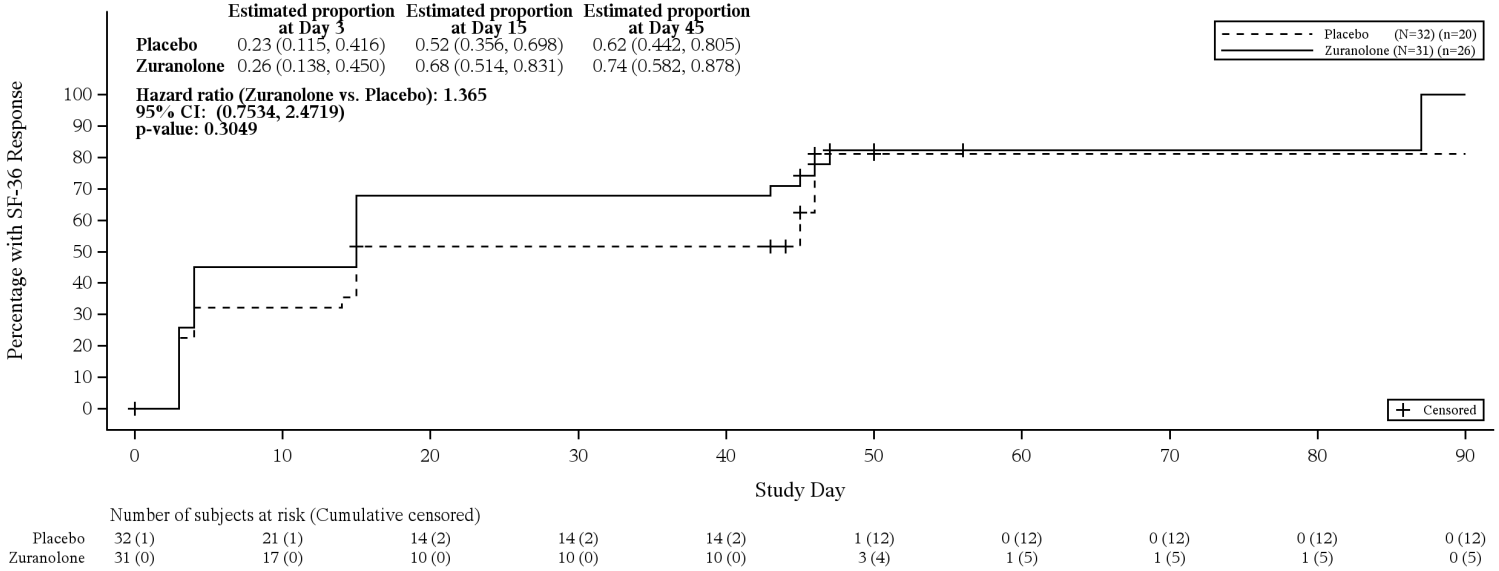
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Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-by.sas:f-sf36-bp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

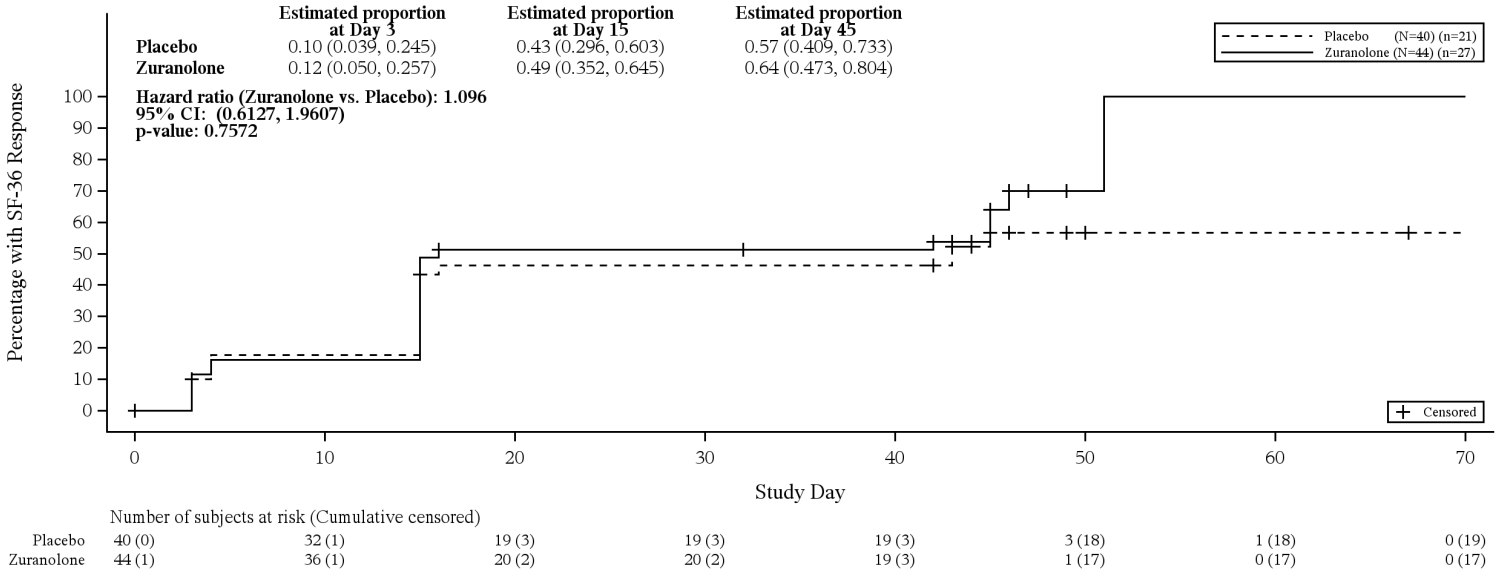
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

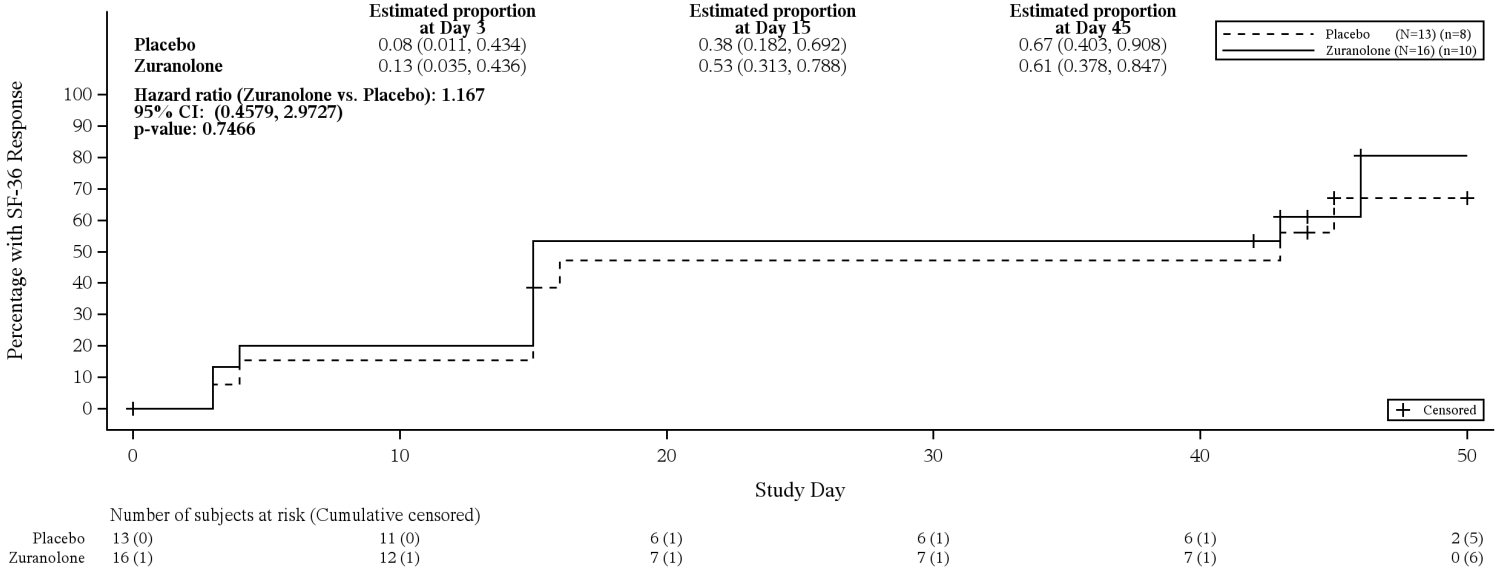
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	13 (0)	11 (0)	6 (1)	6 (1)	6 (1)	2 (5)
Zuranolone	16 (1)	12 (1)	7 (1)	7 (1)	7 (1)	0 (6)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

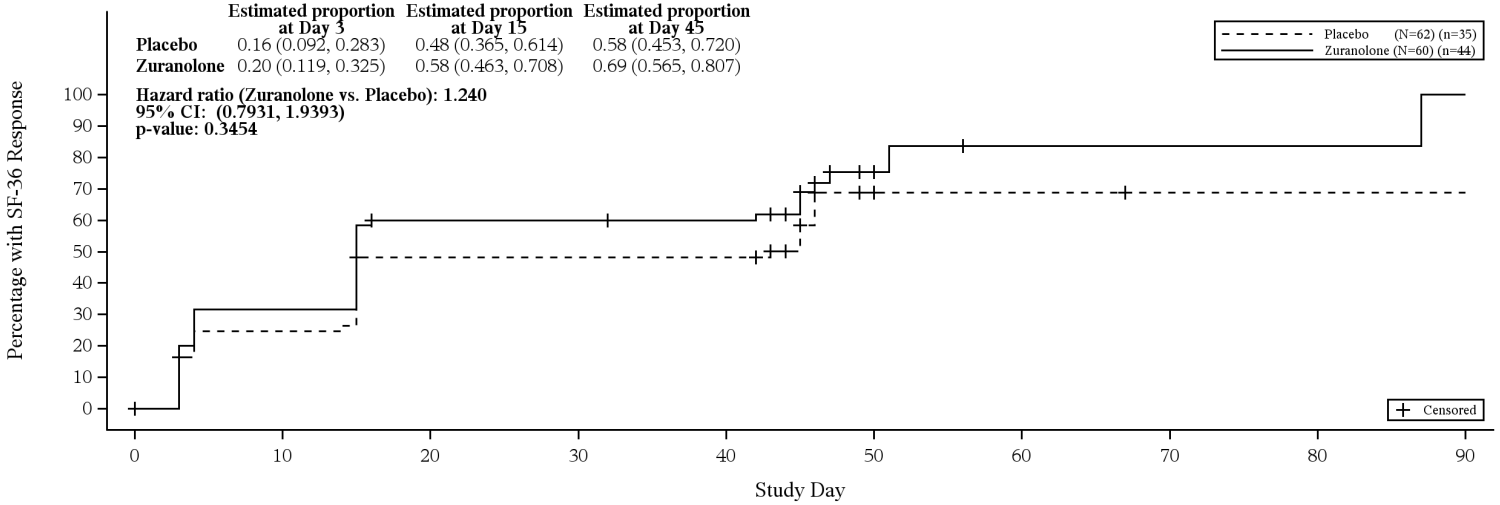
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Number of subjects at risk (Cumulative censored)

Placebo	62 (1)	45 (2)	29 (4)	29 (4)	29 (4)	2 (26)	1 (26)	0 (27)	0 (27)	0 (27)
Zuranolone	60 (0)	41 (0)	23 (1)	23 (1)	22 (2)	4 (15)	1 (16)	1 (16)	1 (16)	0 (16)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

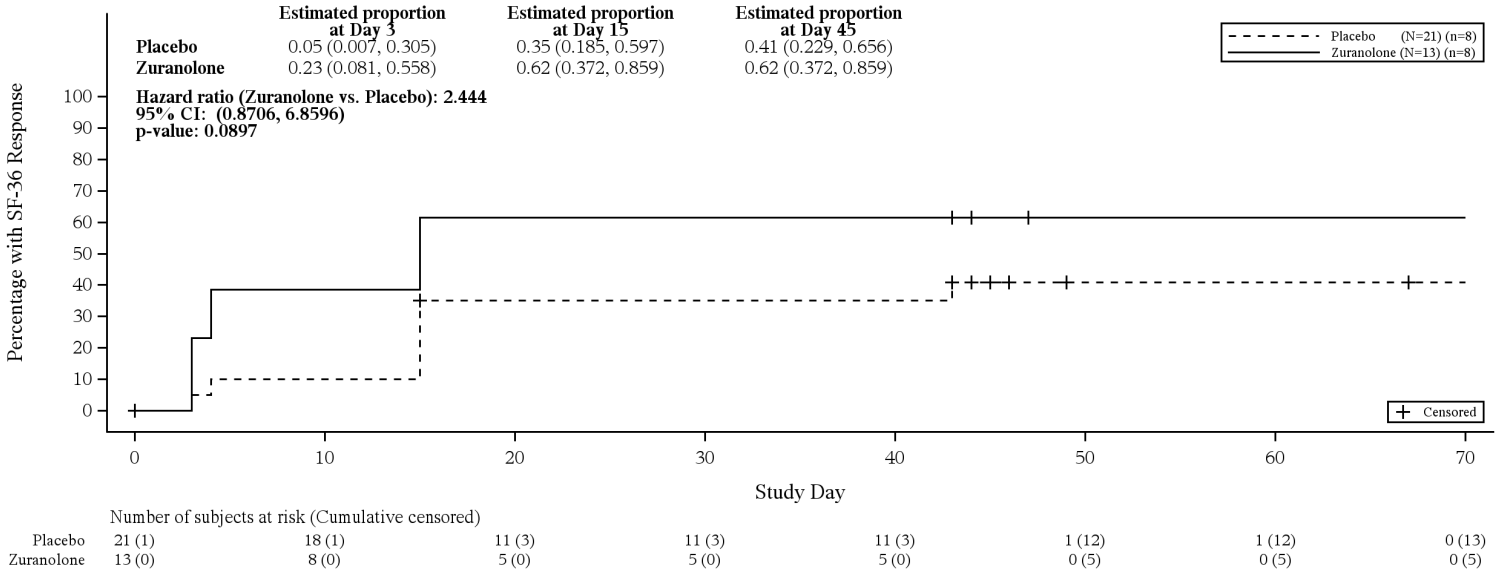
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

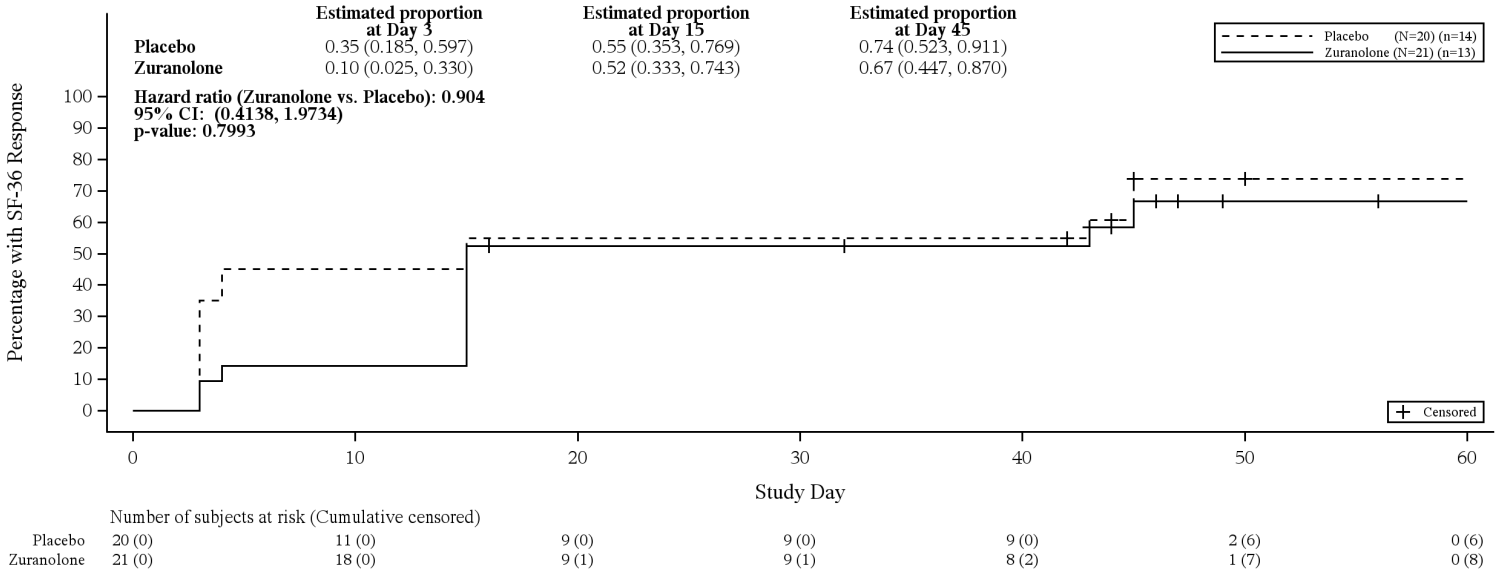
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Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-by.sas:f-sf36-bp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

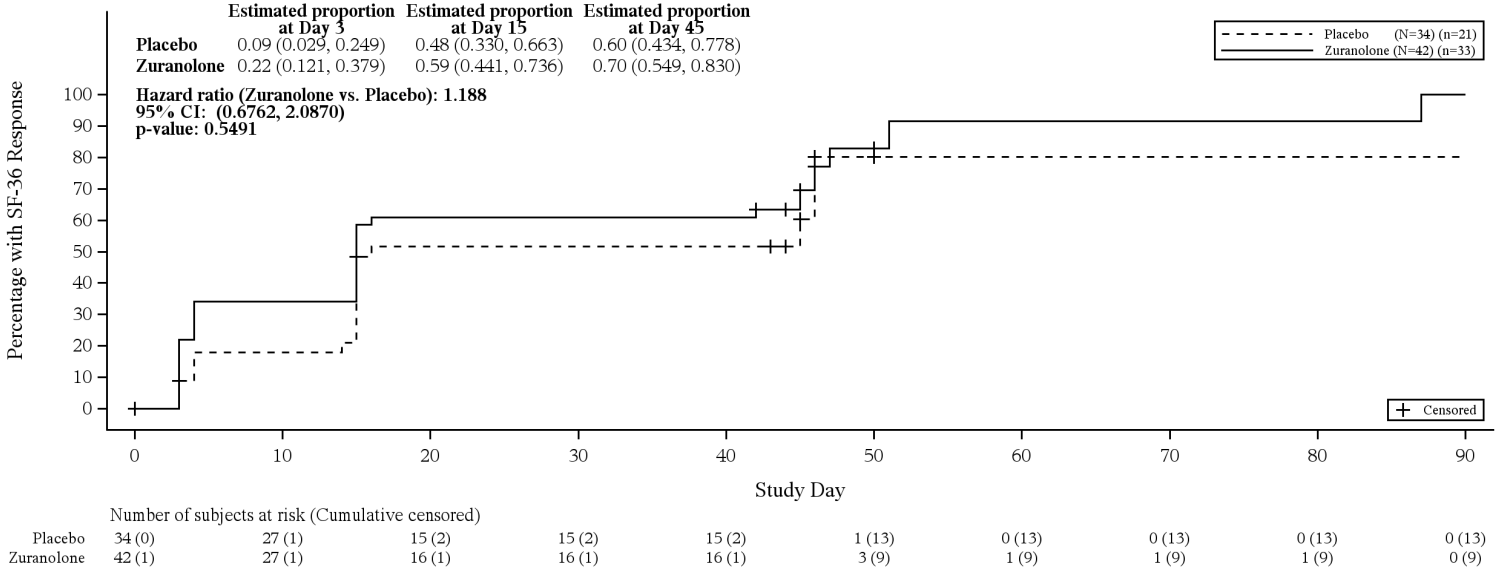
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Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-by.sas:f-sf36-bp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

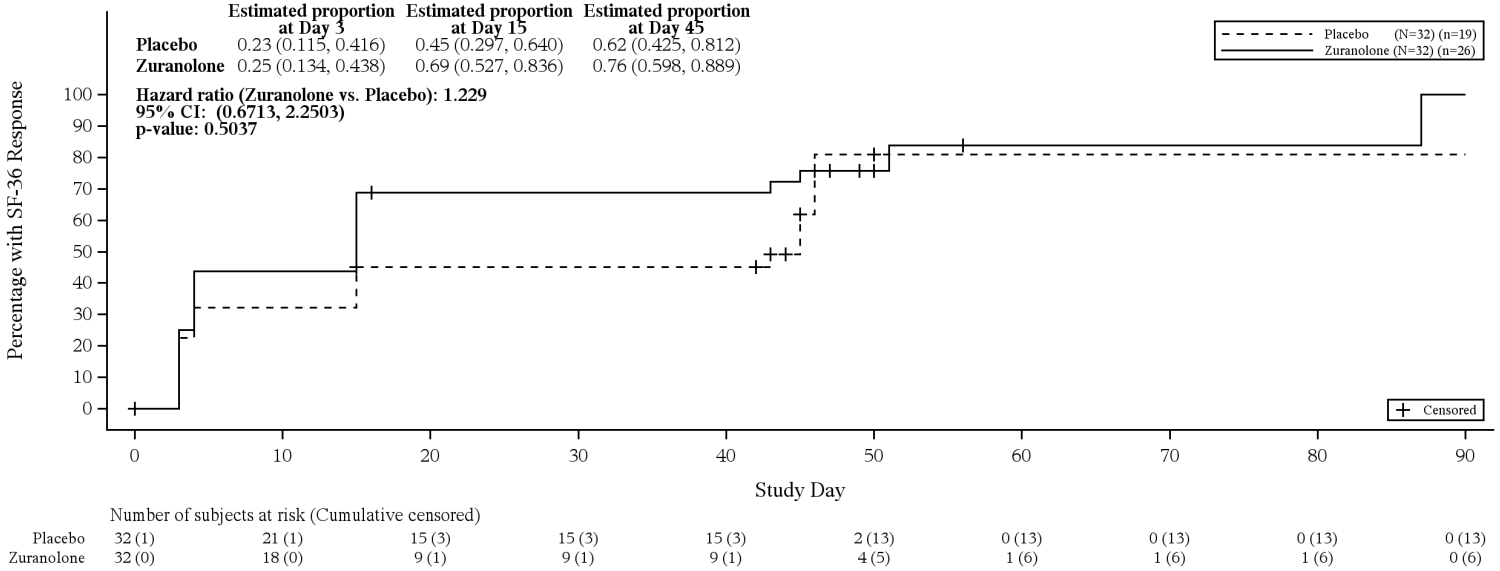
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Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-by.sas:f-sf36-bp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

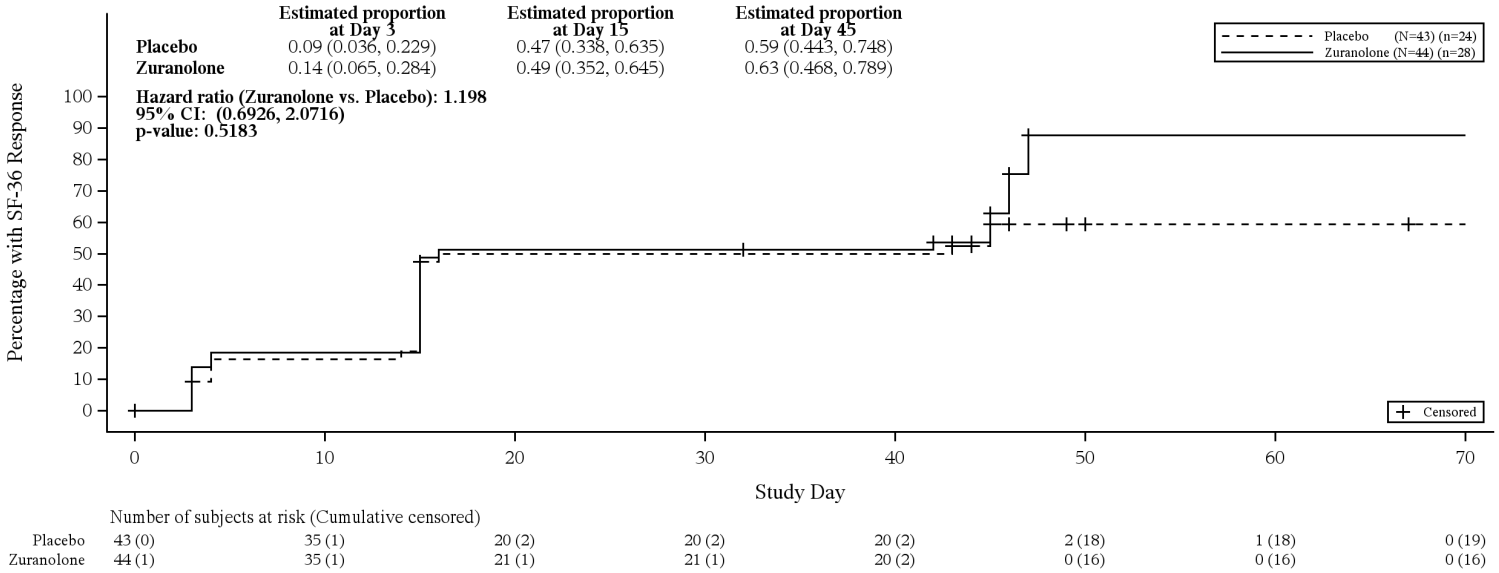
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Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 13 of 17

Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

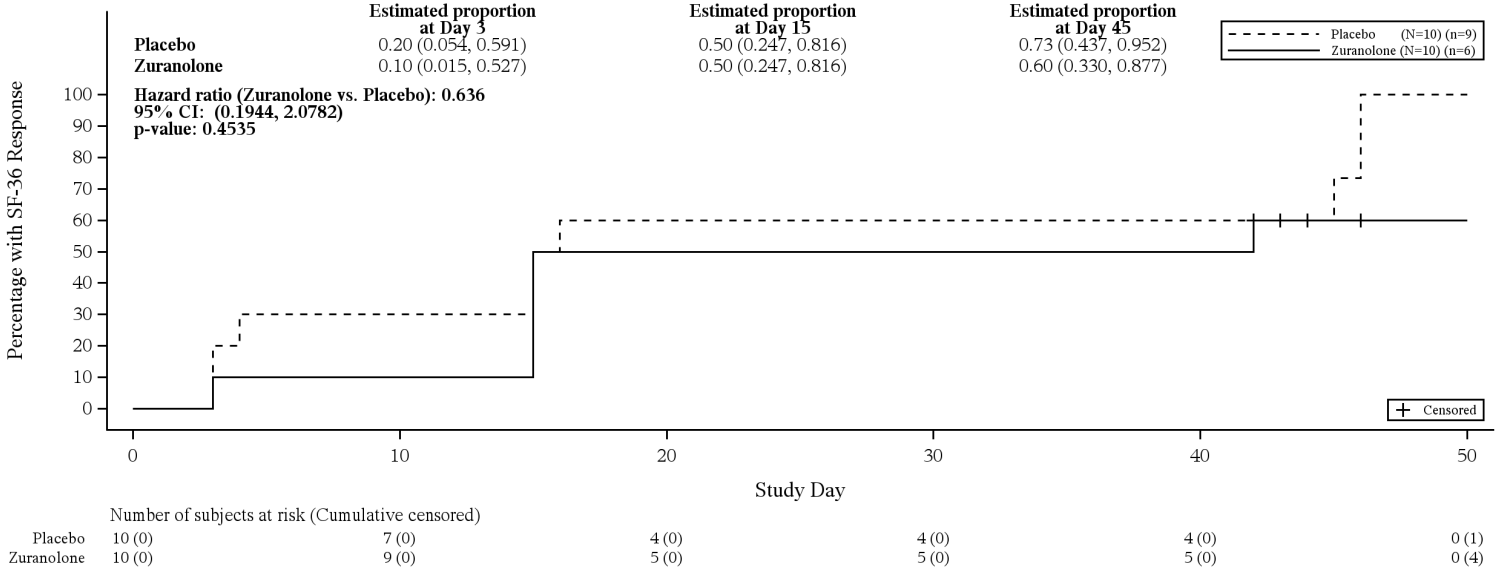
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-by.sas:f-sf36-bp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Number of subjects at risk (Cumulative censored)

Placebo	10 (0)	7 (0)	4 (0)	4 (0)	4 (0)	0 (1)
Zuranolone	10 (0)	9 (0)	5 (0)	5 (0)	5 (0)	0 (4)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

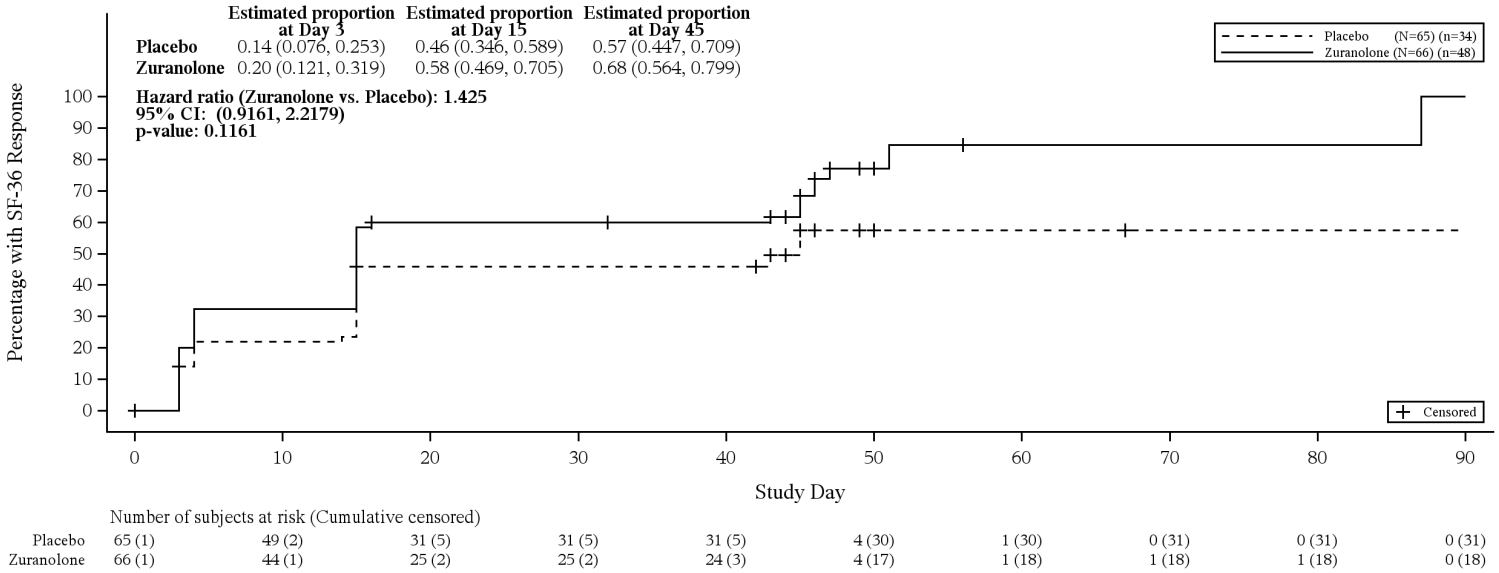
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-by.sas:f-sf36-bp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

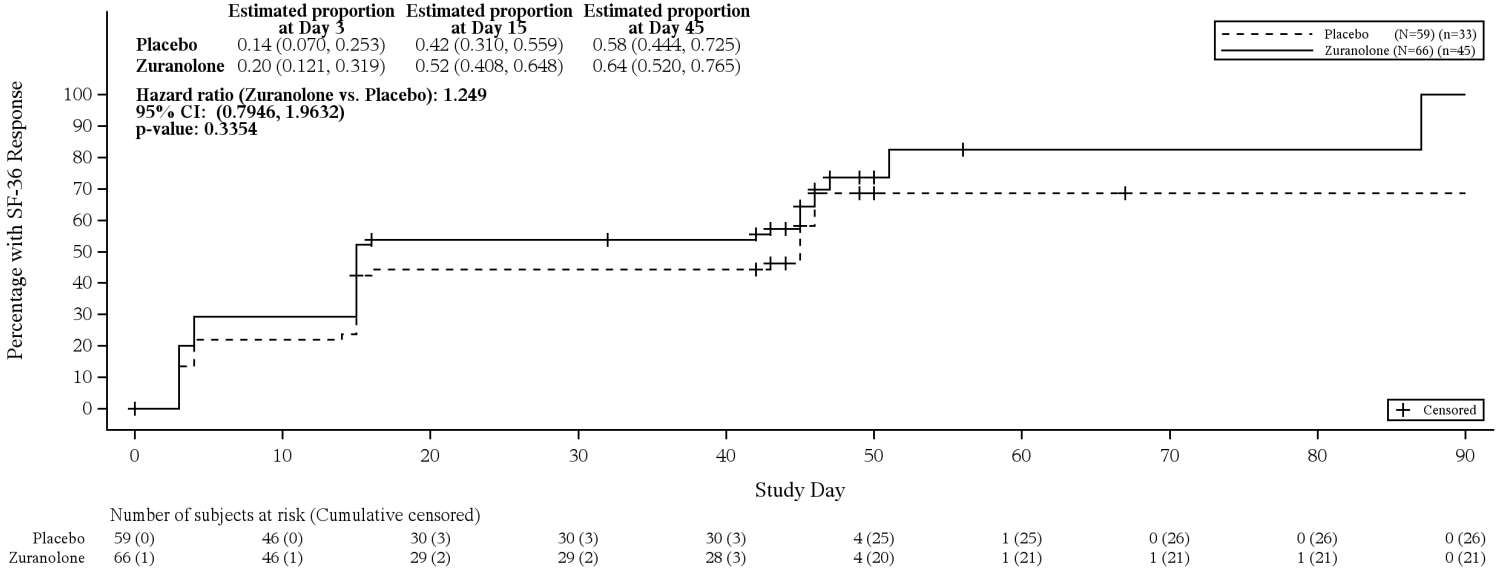
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-by.sas:f-sf36-bp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

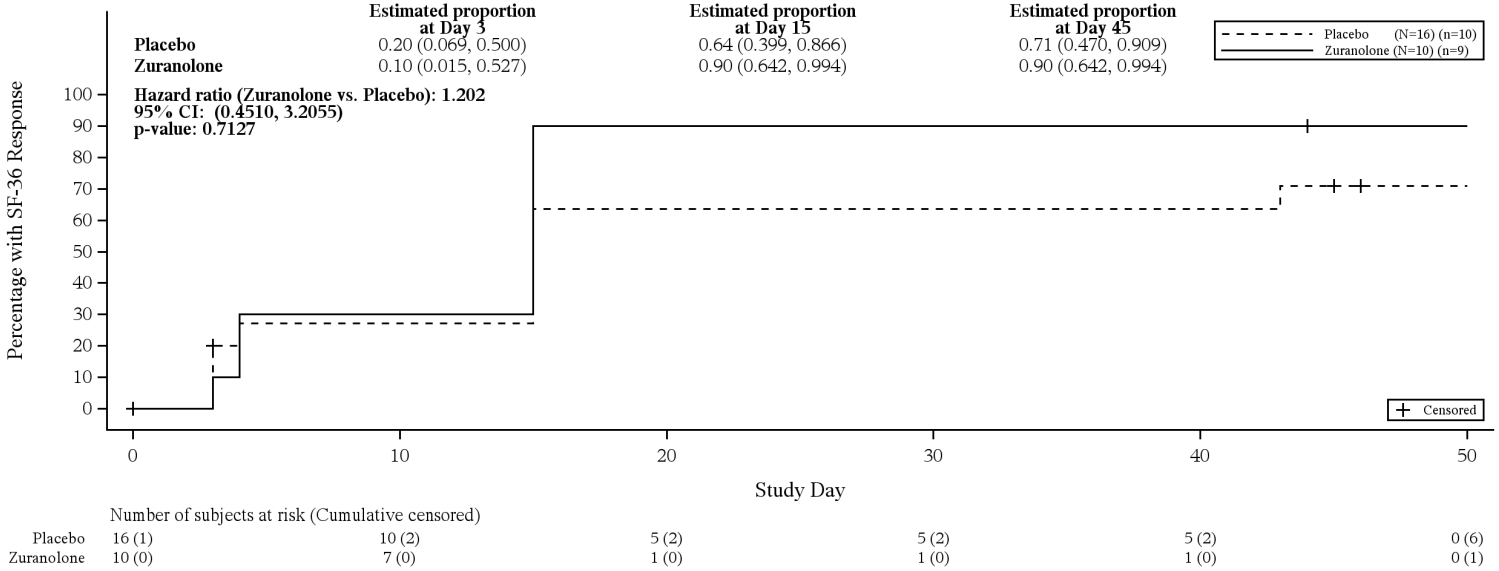
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-by.sas:f-sf36-bp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-bp-resp15-tte-201-by.sas:f-sf36-bp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

2.5.3 Verschlechterung

2.5.3.1 Responder-Analysen

2.5.3.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with worsening, n (%) [2]	13 (17.3)	6 (7.9)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.490
95% CI for the RR		(0.202, 1.193)
p-value for RR		0.1163
OR - Odds Ratio (Zuranolone vs. Placebo)		0.424
95% CI for the OR		(0.147, 1.223)
p-value for OR		0.1126
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.
[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Bodily Pain subscale score worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-bp-wors15-201-ovr.sas:t-sf36-bp-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	8 (10.7)	5 (6.6)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.664
95% CI for the RR		(0.228, 1.931)
p-value for RR		0.4524
OR - Odds Ratio (Zuranolone vs. Placebo)		0.631
95% CI for the OR		(0.189, 2.107)
p-value for OR		0.4538
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Bodily Pain subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing SF-36 Bodily Pain subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Bodily Pain subscale score worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-bp-wors15-201-ovr.sas:t-sf36-bp-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.5.3.1 .2 Subgruppen

2.5.3.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	13 (17.3)	6 (7.9)	
Number of subjects with response at Day 45, n (%)	8 (10.7)	5 (6.6)	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	5/25 (20.0)	1/17 (5.9)	
25 - 45, n / N (%)	8/50 (16.0)	5/59 (8.5)	
Day 45			
18 - 24, n / N (%)	5/25 (20.0)	1/17 (5.9)	
25 - 45, n / N (%)	3/50 (6.0)	4/59 (6.8)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-wors15-201-int.sas:t-sf36-bp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.1868
Day 15			
<28, n / N (%)	1/22 (4.5)	4/30 (13.3)	
>=28, n / N (%)	12/53 (22.6)	2/46 (4.3)	
Day 45			
<28, n / N (%)	2/22 (9.1)	1/30 (3.3)	
>=28, n / N (%)	6/53 (11.3)	4/46 (8.7)	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	3/32 (9.4)	3/31 (9.7)	
White, n / N (%)	9/40 (22.5)	3/44 (6.8)	
Day 45			
Black or African American, n / N (%)	3/32 (9.4)	1/31 (3.2)	
White, n / N (%)	5/40 (12.5)	4/44 (9.1)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-wors15-201-int.sas:t-sf36-bp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.1982
Day 15			
Yes, n / N (%)	3/13 (23.1)	0/16	
No, n / N (%)	10/62 (16.1)	6/60 (10.0)	
Day 45			
Yes, n / N (%)	2/13 (15.4)	1/16 (6.3)	
No, n / N (%)	6/62 (9.7)	4/60 (6.7)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.

NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.

NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-bp-wors15-201-int.sas:t-sf36-bp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	5/21 (23.8)	2/13 (15.4)	
25-29.9, n / N (%)	2/20 (10.0)	2/21 (9.5)	
>=30, n / N (%)	6/34 (17.6)	2/42 (4.8)	
Day 45			
<=24.9, n / N (%)	4/21 (19.0)	2/13 (15.4)	
25-29.9, n / N (%)	0/20	2/21 (9.5)	
>=30, n / N (%)	4/34 (11.8)	1/42 (2.4)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-wors15-201-int.sas:t-sf36-bp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	6/32 (18.8)	3/32 (9.4)	
Postpartum, n / N (%)	7/43 (16.3)	3/44 (6.8)	
Day 45			
3rd Trimester, n / N (%)	1/32 (3.1)	2/32 (6.3)	
Postpartum, n / N (%)	7/43 (16.3)	3/44 (6.8)	
Family History of PPD			NE
Day 15			
Yes, n / N (%)	0/10	1/10 (10.0)	
No/Unknown, n / N (%)	13/65 (20.0)	5/66 (7.6)	
Day 45			
Yes, n / N (%)	0/10	1/10 (10.0)	
No/Unknown, n / N (%)	8/65 (12.3)	4/66 (6.1)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.

NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.

NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-bp-wors15-201-int.sas:t-sf36-bp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Bodily Pain Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.2111
Day 15			
1st Episode, n / N (%)	11/59 (18.6)	5/66 (7.6)	
Recurrent Episode, n / N (%)	2/16 (12.5)	1/10 (10.0)	
Day 45			
1st Episode, n / N (%)	8/59 (13.6)	4/66 (6.1)	
Recurrent Episode, n / N (%)	0/16	1/10 (10.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	1/8 (12.5)	0/10	
>=20, n / N (%)	12/67 (17.9)	6/66 (9.1)	
Day 45			
<20, n / N (%)	2/8 (25.0)	1/10 (10.0)	
>=20, n / N (%)	6/67 (9.0)	4/66 (6.1)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis. NE: Not estimable due to model non-convergence across all four tested models.

NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.

NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-bp-wors15-201-int.sas:t-sf36-bp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

2.5.3.1 .2 .2 Subgruppenanalysen

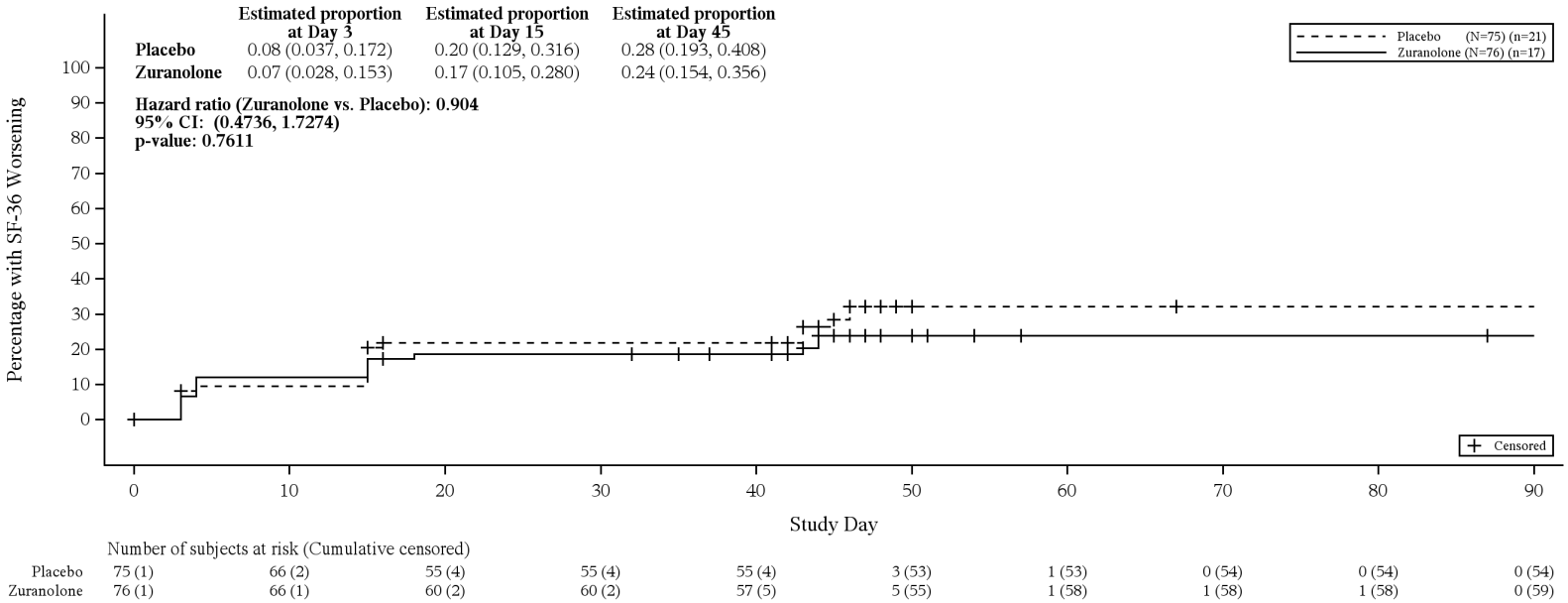
Nicht zutreffend.

2.5.3.2 TTE-Analysen

2.5.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-bp-wors15-tte-201-ovr.sas:f-sf36-bp-wors15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	21 (28.0)	17 (22.4)
Time to first Bodily Pain Subscale worsening (days) [3]		
25th percentile - Q1 (95% CI)	43.0 (15.0, NE)	NE (15.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.904
95% CI for the HR		(0.4736 , 1.7274)
p-value for the HR		0.7611

NOTE 1: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) worsening. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-bp-wors15-tte-201-ovr.sas:t-sf36-bp-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.5.3.2 .2 Subgruppen

2.5.3.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	21 (28.0)	17 (22.4)	
Age Group (years)			
18 - 24, n / N (%)	9/25 (36.0)	3/17 (17.6)	0.5617
25 - 45, n / N (%)	12/50 (24.0)	14/59 (23.7)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	3/22 (13.6)	7/30 (23.3)	0.1825
>=28, n / N (%)	18/53 (34.0)	10/46 (21.7)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	6/32 (18.8)	7/31 (22.6)	0.4833
White, n / N (%)	14/40 (35.0)	10/44 (22.7)	
Antidepressant Use at Baseline			
Yes, n / N (%)	5/13 (38.5)	6/16 (37.5)	0.2697
No, n / N (%)	16/62 (25.8)	11/60 (18.3)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-wors15-tte-201-int.sas:t-sf36-bp-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Bodily Pain Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	8/21 (38.1)	4/13 (30.8)	0.2280(a)
25-29.9, n / N (%)	3/20 (15.0)	7/21 (33.3)	0.5514(b)
>=30, n / N (%)	10/34 (29.4)	6/42 (14.3)	0.0668(c)
Onset of PPD			
3rd Trimester, n / N (%)	7/32 (21.9)	6/32 (18.8)	0.6644
Postpartum, n / N (%)	14/43 (32.6)	11/44 (25.0)	
Family History of PPD			
Yes, n / N (%)	0/10	3/10 (30.0)	0.9889
No/Unknown, n / N (%)	21/65 (32.3)	14/66 (21.2)	
History of PPD			
1st Episode, n / N (%)	19/59 (32.2)	13/66 (19.7)	0.0739
Recurrent Episode, n / N (%)	2/16 (12.5)	4/10 (40.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	3/8 (37.5)	3/10 (30.0)	NA
>=20, n / N (%)	18/67 (26.9)	14/66 (21.2)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-bp-wors15-tte-201-int.sas:t-sf36-bp-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.5.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

2.5.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

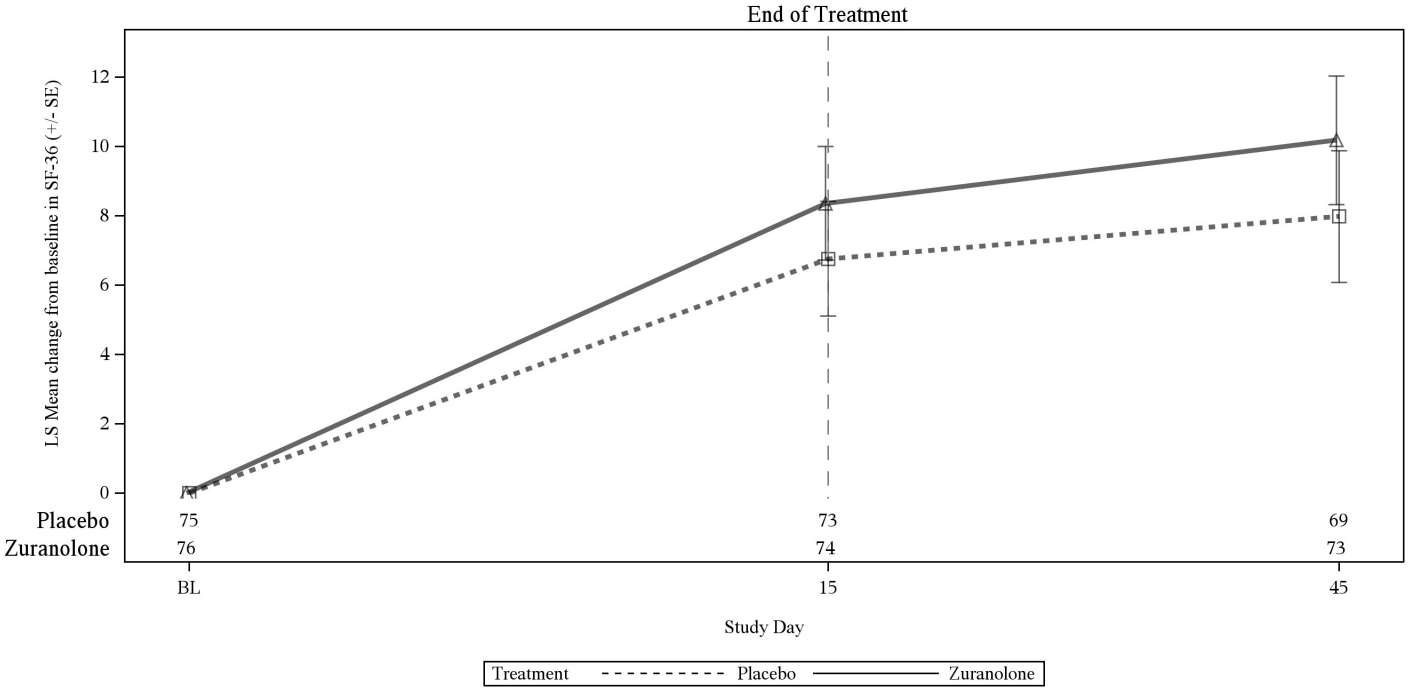
2.6 allg. Gesundheitswahrnehmung

2.6.1 MMRM

2.6.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-ovr.sas:f-sf36-gh-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale: 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	6.76 (1.654)	8.36 (1.639)
95% CI for the LS Mean	3.49, 10.03	5.12, 11.60
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.60 (2.329)
95% CI for the LS Mean		-3.00, 6.21
p-value		0.4920
Hedges' g (Zuranolone vs. Placebo)		0.113
95% CI for Hedges' g		-0.2105, 0.4366
Day 45		
n	69	73
LS Mean (SE)	7.98 (1.898)	10.18 (1.854)
95% CI for the LS Mean	4.23, 11.74	6.52, 13.85
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.20 (2.654)
95% CI for the LS Mean		-3.05, 7.45
p-value		0.4088
Hedges' g (Zuranolone vs. Placebo)		0.138
95% CI for Hedges' g		-0.1911, 0.4678

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-ovr.sas:t-sf36-gh-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.6.1.2 Subgruppen

2.6.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.5546
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.2330
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.3411
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.6737
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-int.sas:t-sf36-gh-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.6031(a)
25-29.9	20	21	0.8317(b)
>=30	34	42	0.6899(c)
Onset of PPD			
3rd Trimester	32	32	0.6357
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.9906
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.2201
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-int.sas:t-sf36-gh-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

2.6.1.2 .2 Subgruppenanalysen

2.6.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	5.74 (2.376)	3.92 (2.902)
95% CI for the LS Mean	0.94, 10.55	-1.95, 9.79
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.82 (3.796)
95% CI for the LS Mean		-9.50, 5.86
p-value		0.6335
Hedges' g (Zuranolone vs. Placebo)		-0.148
95% CI for Hedges' g		-0.7652, 0.4687
Day 45		
n	25	16
LS Mean (SE)	3.66 (3.378)	2.46 (4.221)
95% CI for the LS Mean	-3.17, 10.50	-6.07, 11.00
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.20 (5.436)
95% CI for the LS Mean		-12.19, 9.79
p-value		0.8261
Hedges' g (Zuranolone vs. Placebo)		-0.069
95% CI for Hedges' g		-0.6971, 0.5582

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Age Group: 217-PPD-201B - ITT population

Page: 2 of 2

Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	7.49 (2.162)	9.42 (1.977)
95% CI for the LS Mean	3.20, 11.77	5.50, 13.34
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.93 (2.936)
95% CI for the LS Mean		-3.89, 7.76
p-value		0.5116
Hedges' g (Zuranolone vs. Placebo)		0.128
95% CI for Hedges' g		-0.2563, 0.5124
Day 45		
n	44	57
LS Mean (SE)	10.63 (2.220)	12.23 (1.976)
95% CI for the LS Mean	6.23, 15.03	8.31, 16.15
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.60 (2.980)
95% CI for the LS Mean		-4.31, 7.51
p-value		0.5931
Hedges' g (Zuranolone vs. Placebo)		0.107
95% CI for Hedges' g		-0.2868, 0.5004

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.6.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 2

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	9.34 (3.577)	4.86 (3.139)
95% CI for the LS Mean	2.14, 16.54	-1.45, 11.18
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.48 (4.805)
95% CI for the LS Mean		-14.15, 5.19
p-value		0.3559
Hedges' g (Zuranolone vs. Placebo)		-0.261
95% CI for Hedges' g		-0.8222, 0.2993
Day 45		
n	22	28
LS Mean (SE)	10.75 (3.679)	9.44 (3.229)
95% CI for the LS Mean	3.35, 18.15	2.95, 15.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.31 (4.940)
95% CI for the LS Mean		-11.25, 8.63
p-value		0.7921
Hedges' g (Zuranolone vs. Placebo)		-0.074
95% CI for Hedges' g		-0.6329, 0.4843

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 2 of 2

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	6.02 (1.791)	9.94 (1.888)
95% CI for the LS Mean	2.46, 9.57	6.19, 13.69
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.92 (2.611)
95% CI for the LS Mean		-1.26, 9.11
p-value		0.1364
Hedges' g (Zuranolone vs. Placebo)		0.303
95% CI for Hedges' g		-0.0977, 0.7039
Day 45		
n	47	45
LS Mean (SE)	7.22 (2.222)	10.17 (2.283)
95% CI for the LS Mean	2.80, 11.63	5.64, 14.71
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.96 (3.195)
95% CI for the LS Mean		-3.39, 9.30
p-value		0.3571
Hedges' g (Zuranolone vs. Placebo)		0.191
95% CI for Hedges' g		-0.2183, 0.6011

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.6.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	4.71 (2.327)	4.84 (2.325)
95% CI for the LS Mean	0.06, 9.37	0.18, 9.49
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.12 (3.296)
95% CI for the LS Mean		-6.47, 6.72
p-value		0.9705
Hedges' g (Zuranolone vs. Placebo)		0.009
95% CI for Hedges' g		-0.4885, 0.5071
Day 45		
n	30	30
LS Mean (SE)	8.80 (2.690)	6.78 (2.689)
95% CI for the LS Mean	3.41, 14.19	1.39, 12.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.02 (3.809)
95% CI for the LS Mean		-9.65, 5.60
p-value		0.5973
Hedges' g (Zuranolone vs. Placebo)		-0.135
95% CI for Hedges' g		-0.6420, 0.3713

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Race Group: 217-PPD-201B - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	9.08 (2.367)	10.90 (2.271)
95% CI for the LS Mean	4.36, 13.79	6.38, 15.42
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.83 (3.283)
95% CI for the LS Mean		-4.71, 8.37
p-value		0.5794
Hedges' g (Zuranolone vs. Placebo)		0.123
95% CI for Hedges' g		-0.3137, 0.5588
Day 45		
n	36	42
LS Mean (SE)	7.56 (2.802)	12.40 (2.617)
95% CI for the LS Mean	1.98, 13.13	7.19, 17.61
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.84 (3.836)
95% CI for the LS Mean		-2.80, 12.48
p-value		0.2108
Hedges' g (Zuranolone vs. Placebo)		0.284
95% CI for Hedges' g		-0.1636, 0.7311

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.6.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	5.28 (2.873)	9.92 (2.678)
95% CI for the LS Mean	-0.63, 11.20	4.41, 15.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.64 (3.942)
95% CI for the LS Mean		-3.48, 12.75
p-value		0.2506
Hedges' g (Zuranolone vs. Placebo)		0.433
95% CI for Hedges' g		-0.3187, 1.1838
Day 45		
n	11	15
LS Mean (SE)	6.68 (3.930)	10.79 (3.393)
95% CI for the LS Mean	-1.41, 14.76	3.79, 17.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.11 (5.209)
95% CI for the LS Mean		-6.61, 14.83
p-value		0.4377
Hedges' g (Zuranolone vs. Placebo)		0.303
95% CI for Hedges' g		-0.4792, 1.0855

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	7.03 (1.922)	8.03 (1.933)
95% CI for the LS Mean	3.22, 10.83	4.20, 11.85
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.00 (2.726)
95% CI for the LS Mean		-4.40, 6.40
p-value		0.7142
Hedges' g (Zuranolone vs. Placebo)		0.067
95% CI for Hedges' g		-0.2926, 0.4263
Day 45		
n	58	58
LS Mean (SE)	8.19 (2.161)	10.10 (2.161)
95% CI for the LS Mean	3.91, 12.47	5.82, 14.38
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.91 (3.056)
95% CI for the LS Mean		-4.14, 7.96
p-value		0.5331
Hedges' g (Zuranolone vs. Placebo)		0.115
95% CI for Hedges' g		-0.2489, 0.4796

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.6.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	6.99 (2.402)	6.49 (2.983)
95% CI for the LS Mean	2.08, 11.90	0.39, 12.58
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.50 (3.839)
95% CI for the LS Mean		-8.35, 7.34
p-value		0.8963
Hedges' g (Zuranolone vs. Placebo)		-0.046
95% CI for Hedges' g		-0.7440, 0.6527
Day 45		
n	18	12
LS Mean (SE)	6.95 (3.953)	8.21 (4.847)
95% CI for the LS Mean	-1.15, 15.05	-1.71, 18.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.26 (6.268)
95% CI for the LS Mean		-11.57, 14.10
p-value		0.8418
Hedges' g (Zuranolone vs. Placebo)		0.073
95% CI for Hedges' g		-0.6576, 0.8037

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	8.75 (3.543)	12.48 (3.489)
95% CI for the LS Mean	1.56, 15.94	5.41, 19.55
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.73 (4.993)
95% CI for the LS Mean		-6.39, 13.85
p-value		0.4598
Hedges' g (Zuranolone vs. Placebo)		0.232
95% CI for Hedges' g		-0.3903, 0.8534
Day 45		
n	20	20
LS Mean (SE)	9.00 (4.076)	14.48 (4.014)
95% CI for the LS Mean	0.74, 17.26	6.35, 22.61
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.48 (5.737)
95% CI for the LS Mean		-6.14, 17.10
p-value		0.3456
Hedges' g (Zuranolone vs. Placebo)		0.296
95% CI for Hedges' g		-0.3271, 0.9193

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	4.89 (2.548)	7.15 (2.287)
95% CI for the LS Mean	-0.19, 9.97	2.59, 11.71
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.26 (3.427)
95% CI for the LS Mean		-4.57, 9.10
p-value		0.5114
Hedges' g (Zuranolone vs. Placebo)		0.153
95% CI for Hedges' g		-0.3063, 0.6118
Day 45		
n	31	41
LS Mean (SE)	7.61 (2.535)	9.01 (2.222)
95% CI for the LS Mean	2.55, 12.66	4.57, 13.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.40 (3.376)
95% CI for the LS Mean		-5.33, 8.13
p-value		0.6800
Hedges' g (Zuranolone vs. Placebo)		0.098
95% CI for Hedges' g		-0.3692, 0.5643

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.6.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	5.46 (2.555)	7.39 (2.512)
95% CI for the LS Mean	0.34, 10.57	2.37, 12.42
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.94 (3.587)
95% CI for the LS Mean		-5.24, 9.11
p-value		0.5914
Hedges' g (Zuranolone vs. Placebo)		0.134
95% CI for Hedges' g		-0.3601, 0.6288
Day 45		
n	29	30
LS Mean (SE)	6.26 (3.001)	10.11 (2.951)
95% CI for the LS Mean	0.26, 12.27	4.21, 16.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.85 (4.211)
95% CI for the LS Mean		-4.58, 12.28
p-value		0.3645
Hedges' g (Zuranolone vs. Placebo)		0.235
95% CI for Hedges' g		-0.2773, 0.7470

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	7.93 (2.170)	8.98 (2.166)
95% CI for the LS Mean	3.61, 12.25	4.67, 13.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.04 (3.071)
95% CI for the LS Mean		-5.07, 7.15
p-value		0.7348
Hedges' g (Zuranolone vs. Placebo)		0.074
95% CI for Hedges' g		-0.3543, 0.5014
Day 45		
n	40	43
LS Mean (SE)	9.38 (2.512)	10.06 (2.435)
95% CI for the LS Mean	4.39, 14.38	5.21, 14.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.67 (3.503)
95% CI for the LS Mean		-6.30, 7.64
p-value		0.8483
Hedges' g (Zuranolone vs. Placebo)		0.042
95% CI for Hedges' g		-0.3888, 0.4724

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.6.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	7.69 (3.464)	9.20 (3.478)
95% CI for the LS Mean	0.39, 14.99	1.87, 16.53
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.51 (5.001)
95% CI for the LS Mean		-9.01, 12.02
p-value		0.7664
Hedges' g (Zuranolone vs. Placebo)		0.129
95% CI for Hedges' g		-0.7482, 1.0067
Day 45		
n	9	10
LS Mean (SE)	11.18 (2.675)	13.60 (2.499)
95% CI for the LS Mean	5.52, 16.84	8.30, 18.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.42 (3.826)
95% CI for the LS Mean		-5.67, 10.50
p-value		0.5363
Hedges' g (Zuranolone vs. Placebo)		0.277
95% CI for Hedges' g		-0.6277, 1.1820

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	6.58 (1.842)	8.24 (1.822)
95% CI for the LS Mean	2.93, 10.22	4.64, 11.85
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.67 (2.592)
95% CI for the LS Mean		-3.47, 6.80
p-value		0.5219
Hedges' g (Zuranolone vs. Placebo)		0.113
95% CI for Hedges' g		-0.2348, 0.4614
Day 45		
n	60	63
LS Mean (SE)	7.48 (2.163)	9.65 (2.117)
95% CI for the LS Mean	3.20, 11.76	5.45, 13.84
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.17 (3.028)
95% CI for the LS Mean		-3.83, 8.16
p-value		0.4759
Hedges' g (Zuranolone vs. Placebo)		0.128
95% CI for Hedges' g		-0.2257, 0.4821

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.6.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	6.02 (1.851)	8.38 (1.772)
95% CI for the LS Mean	2.35, 9.68	4.87, 11.89
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.36 (2.563)
95% CI for the LS Mean		-2.71, 7.44
p-value		0.3589
Hedges' g (Zuranolone vs. Placebo)		0.165
95% CI for Hedges' g		-0.1891, 0.5195
Day 45		
n	55	64
LS Mean (SE)	7.29 (2.133)	10.97 (1.994)
95% CI for the LS Mean	3.07, 11.51	7.02, 14.91
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.68 (2.920)
95% CI for the LS Mean		-2.11, 9.46
p-value		0.2104
Hedges' g (Zuranolone vs. Placebo)		0.230
95% CI for Hedges' g		-0.1315, 0.5916

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	12.36 (3.466)	5.20 (4.123)
95% CI for the LS Mean	5.13, 19.59	-3.40, 13.80
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-7.16 (5.600)
95% CI for the LS Mean		-18.84, 4.52
p-value		0.2156
Hedges' g (Zuranolone vs. Placebo)		-0.511
95% CI for Hedges' g		-1.3354, 0.3132
Day 45		
n	14	9
LS Mean (SE)	13.29 (4.283)	1.17 (5.293)
95% CI for the LS Mean	4.36, 22.22	-9.80, 12.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-12.12 (6.996)
95% CI for the LS Mean		-26.61, 2.36
p-value		0.0968
Hedges' g (Zuranolone vs. Placebo)		-0.714
95% CI for Hedges' g		-1.5760, 0.1488

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

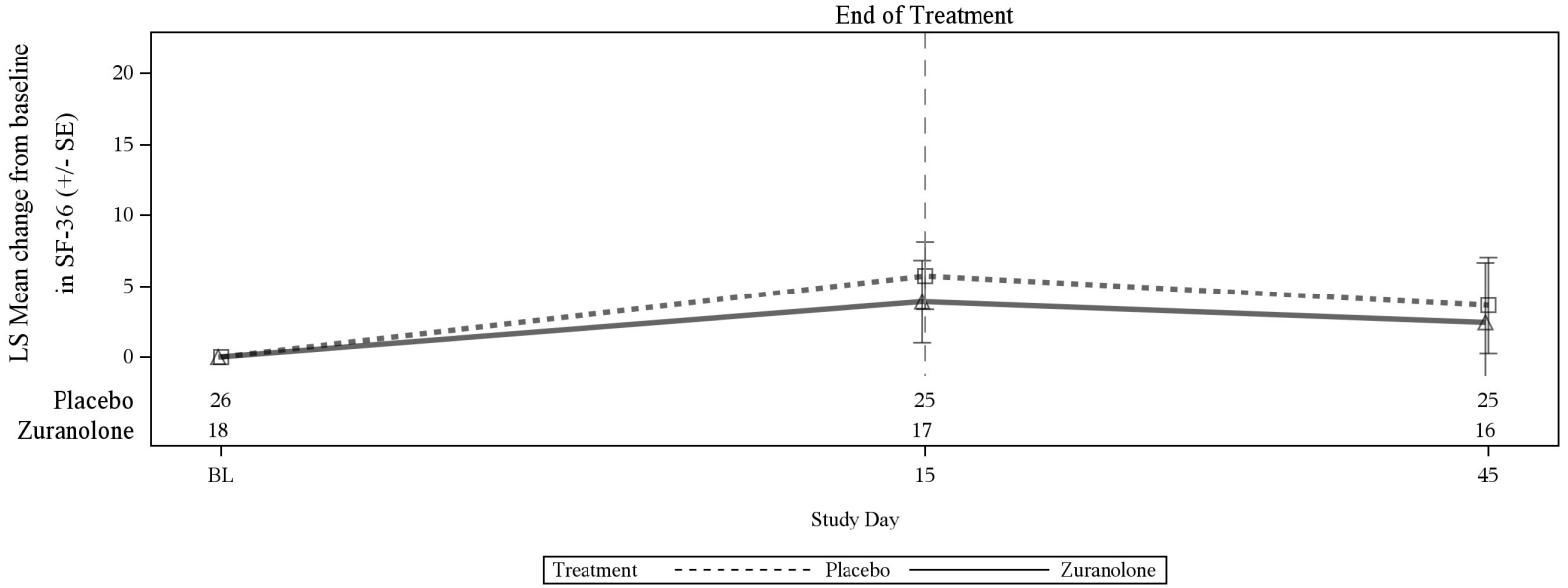
Source: biib125/v_a/germany_amnog/t-sf36-gh-mmrm-201-by.sas:t-sf36-gh-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.6.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

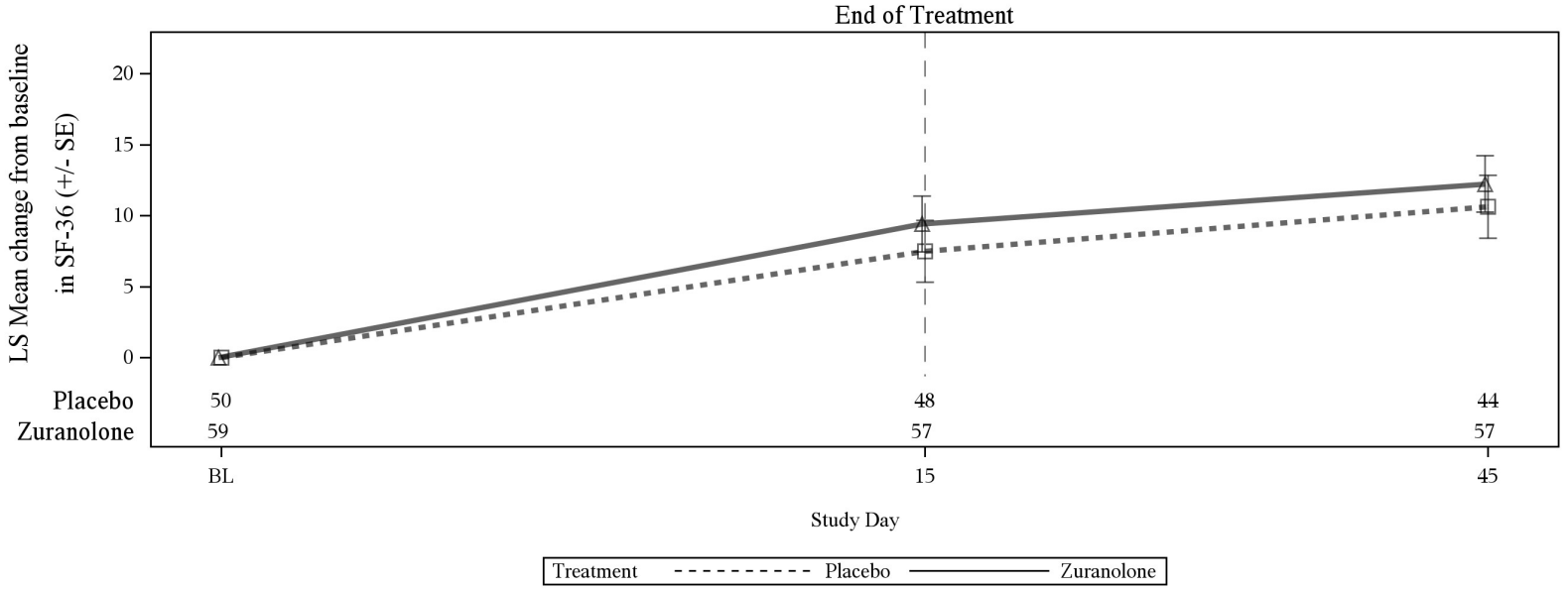
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

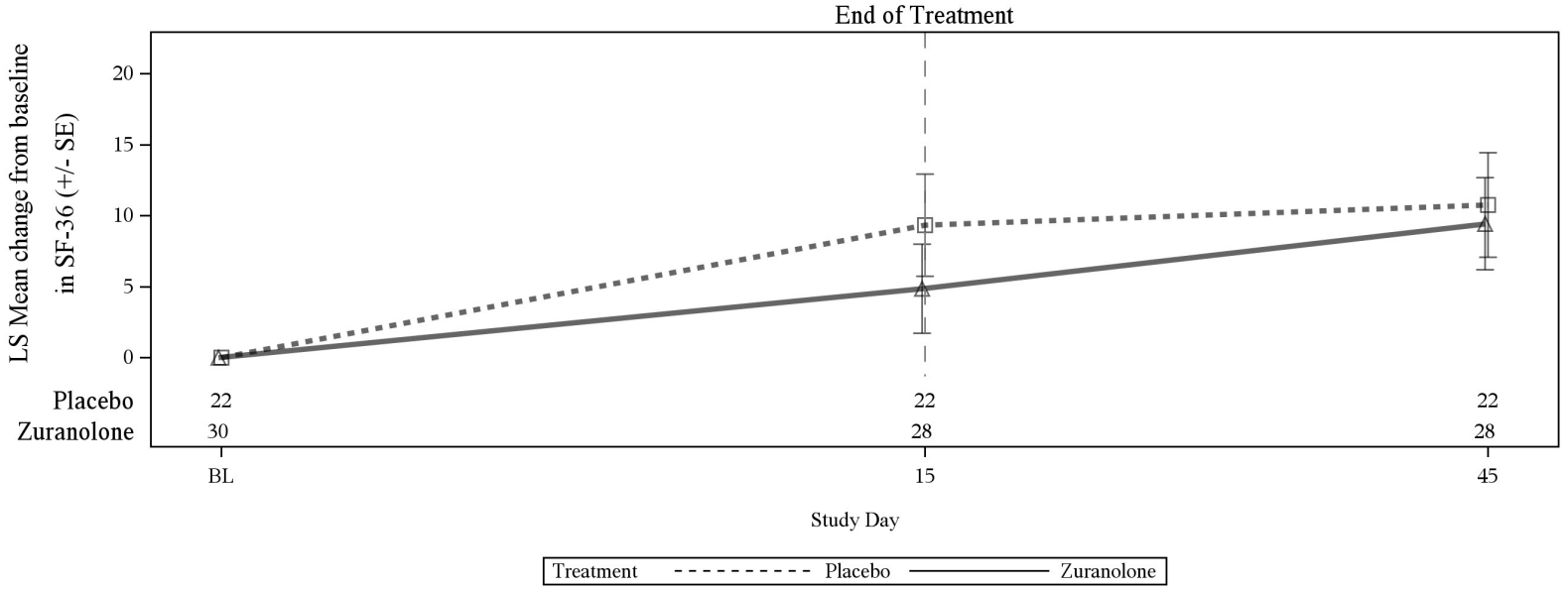
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

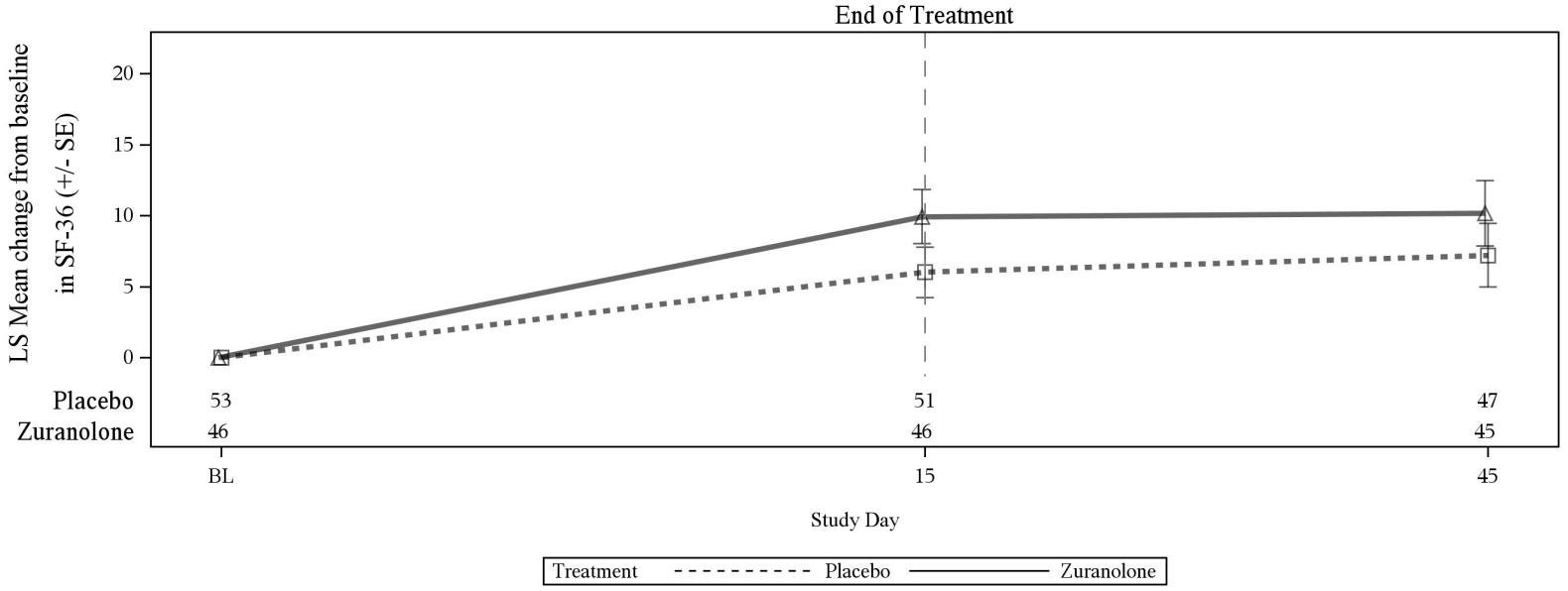
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Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

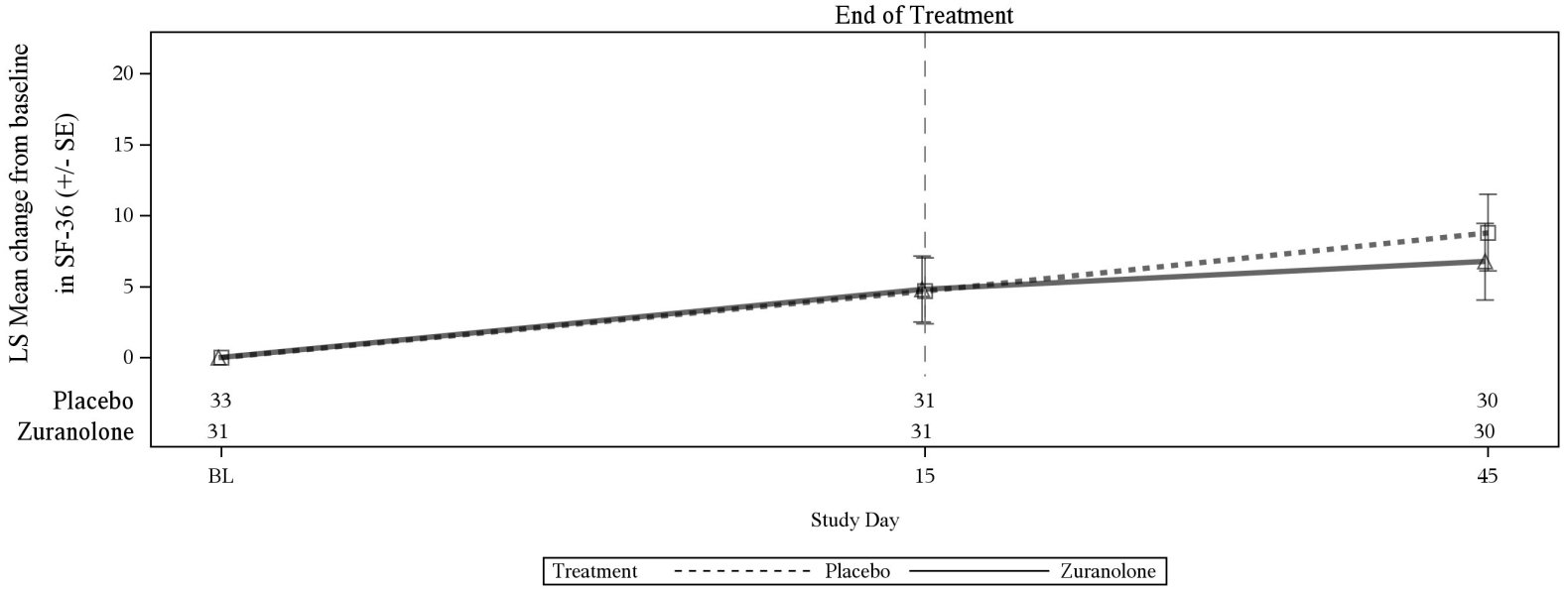
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Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

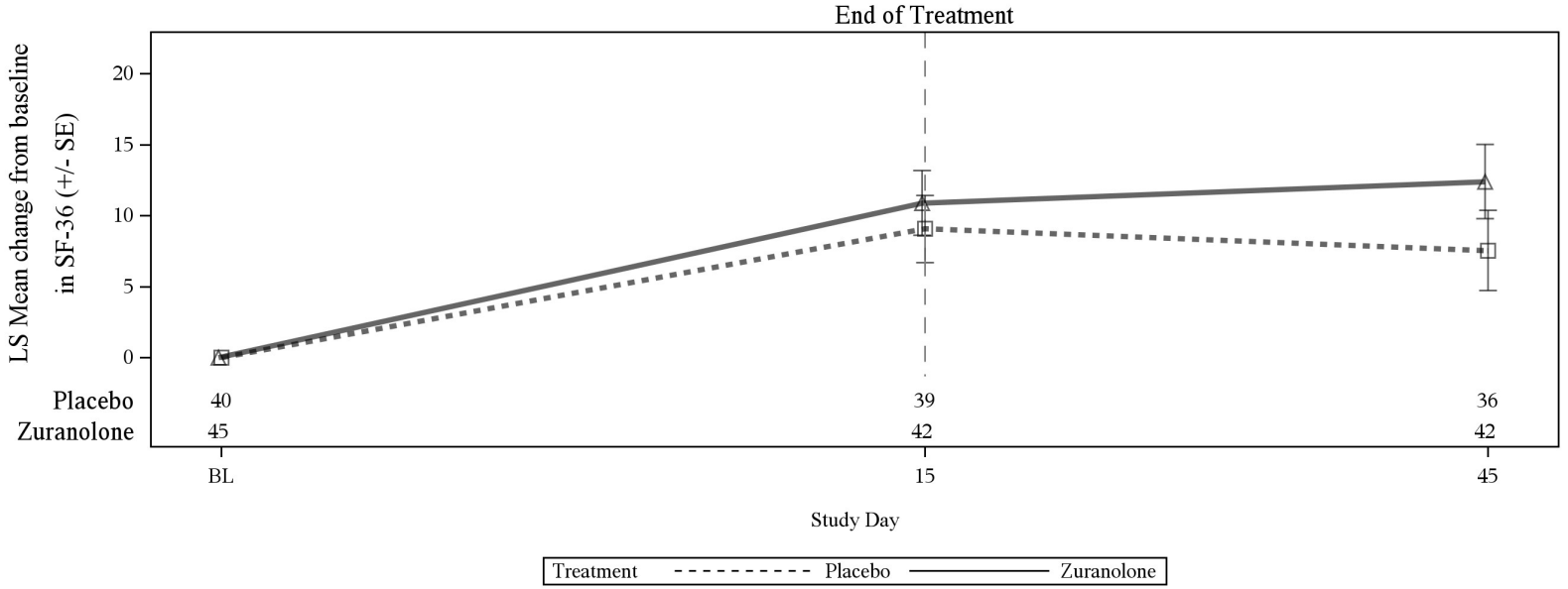
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Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

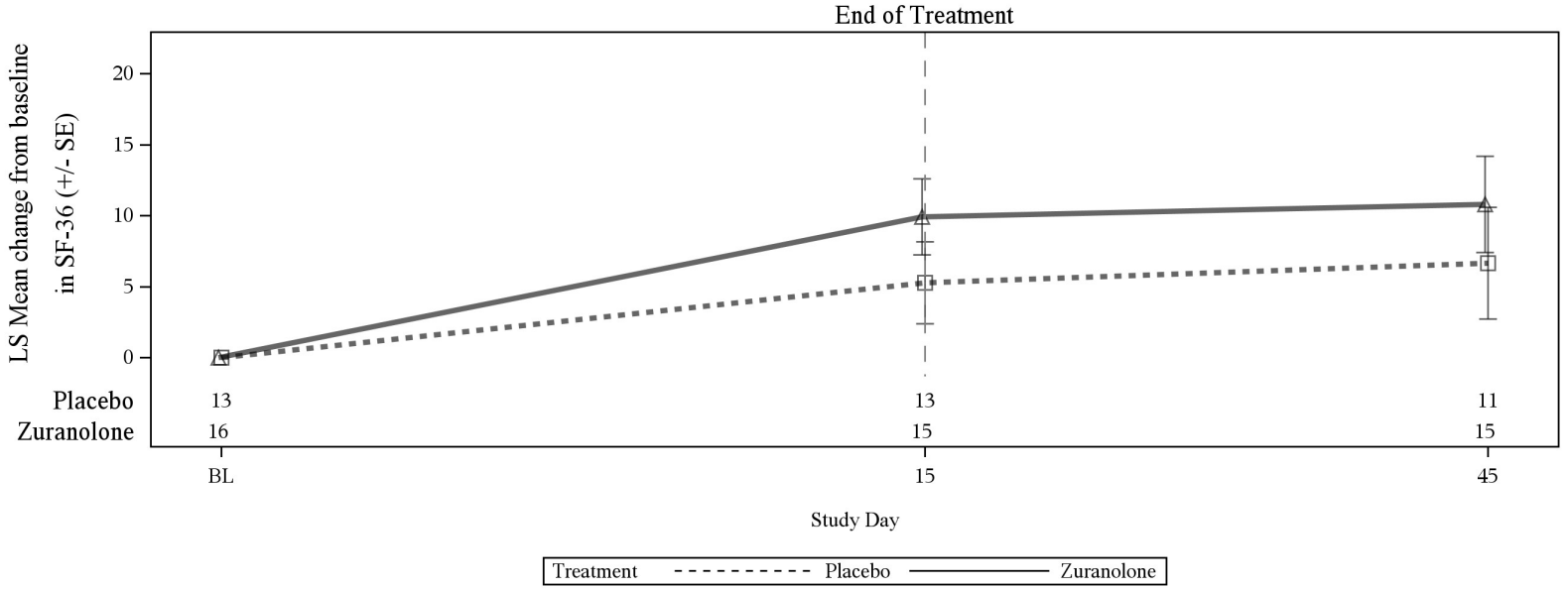
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Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 7 of 17

Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

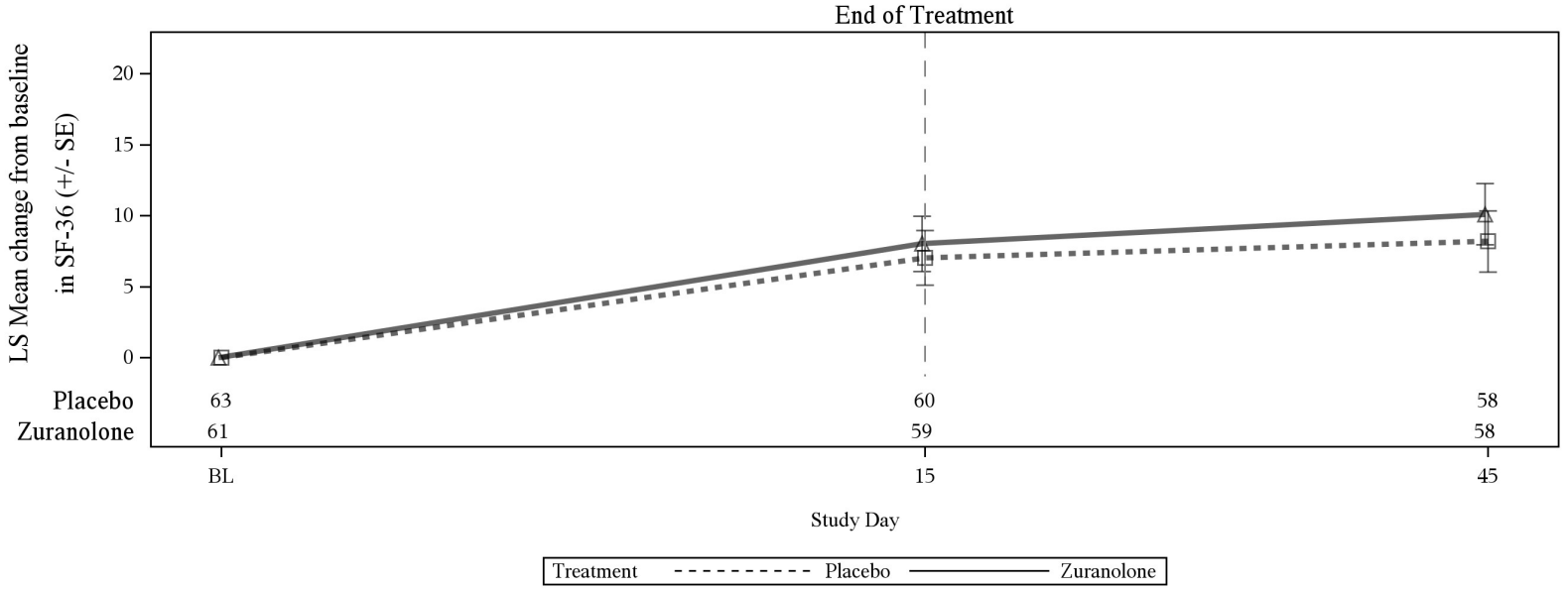
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

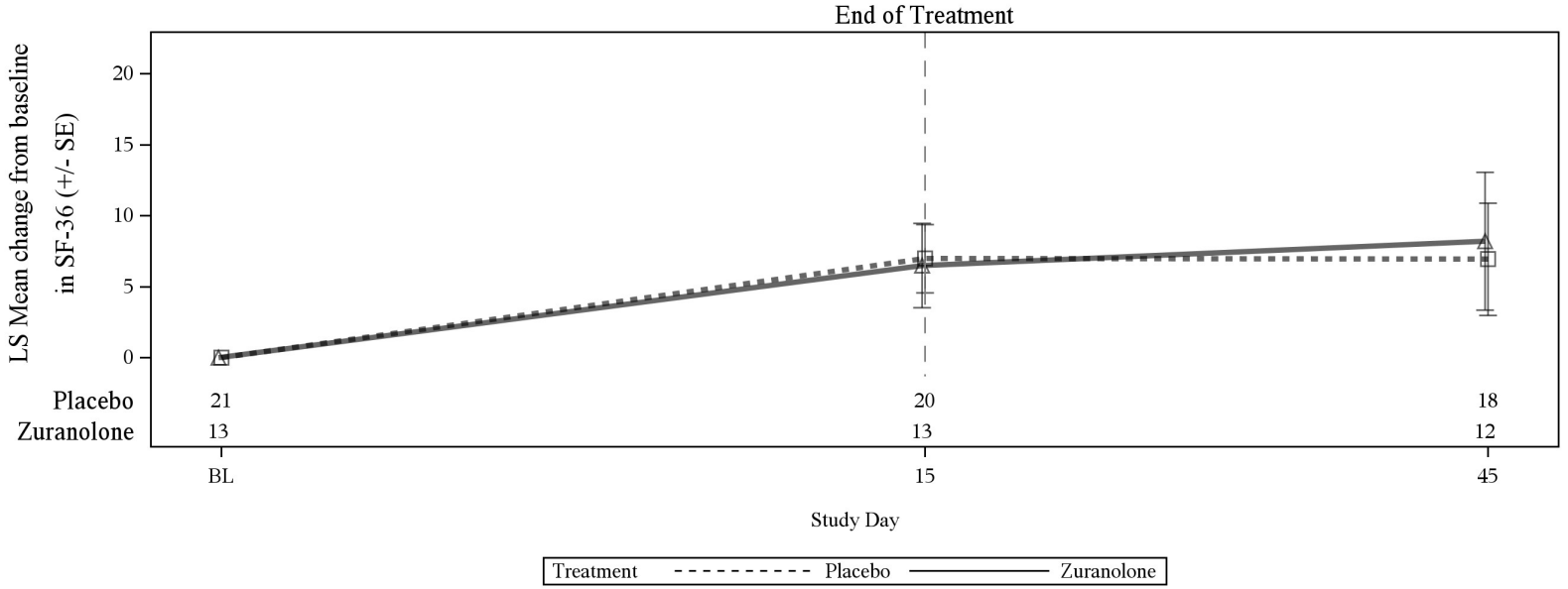
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Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 9 of 17

BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

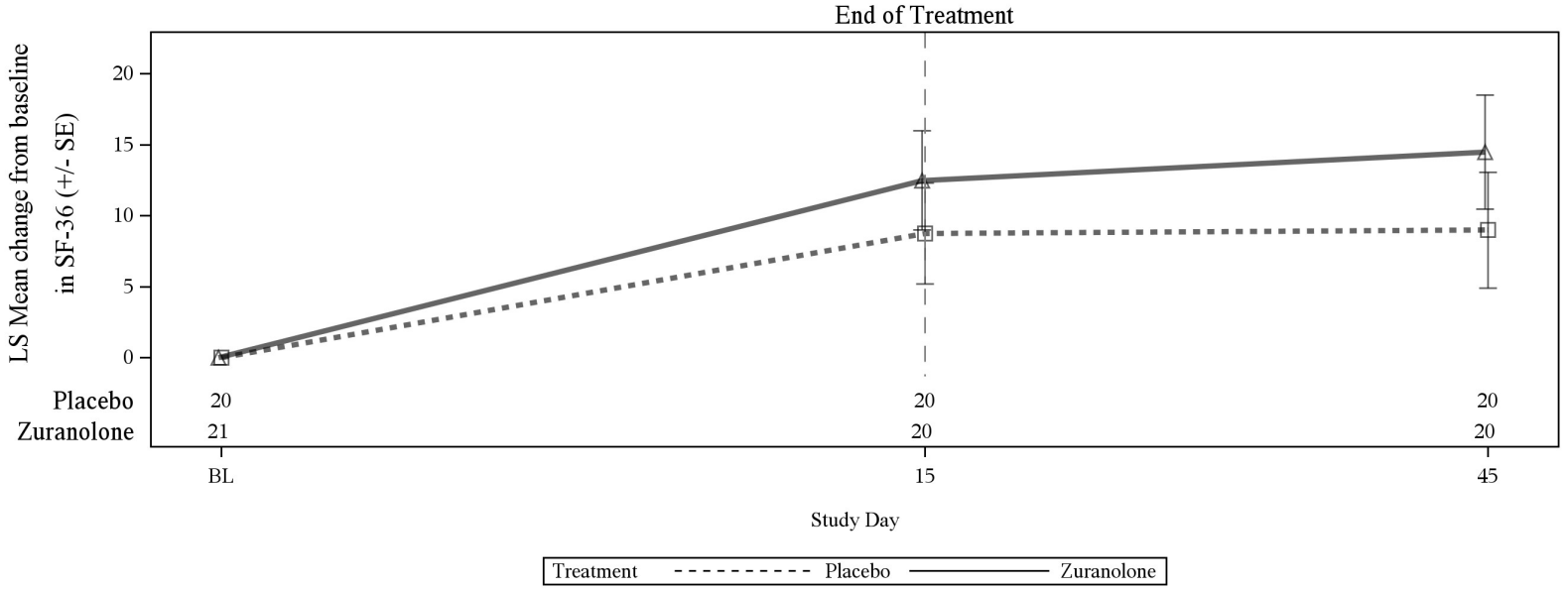
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Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 10 of 17

BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

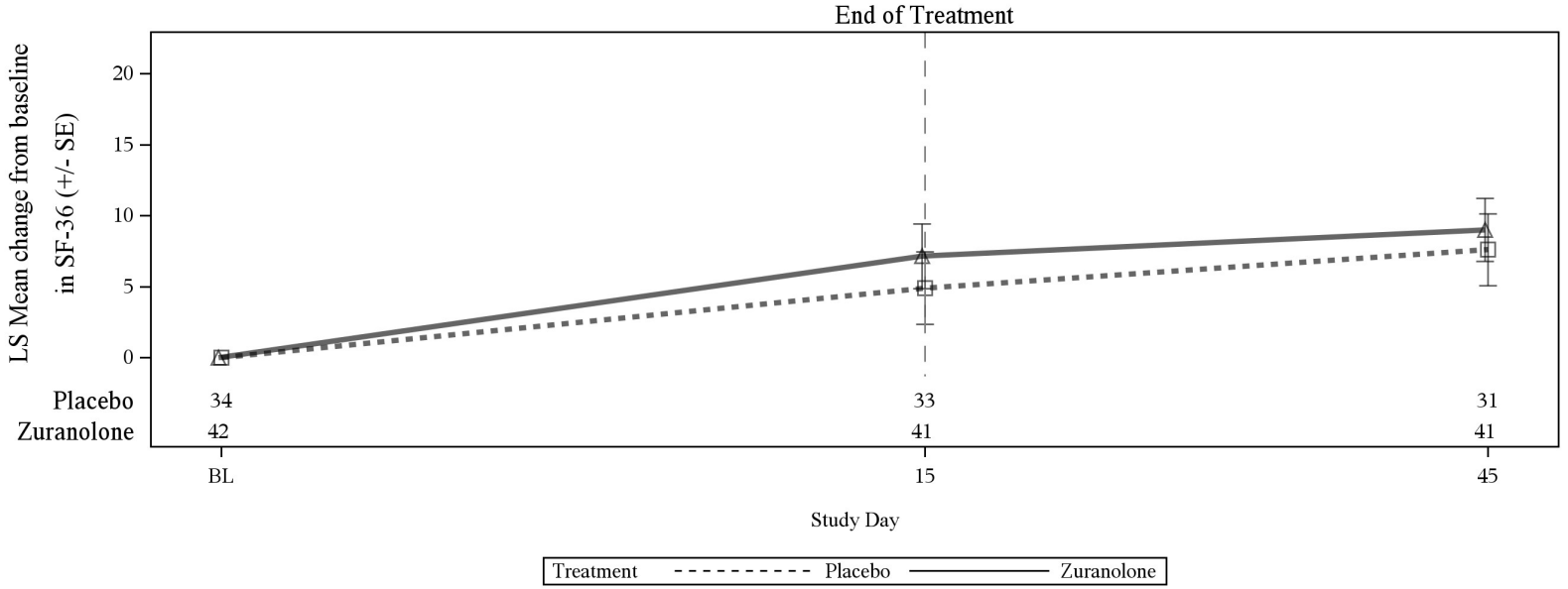
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Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 11 of 17

BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

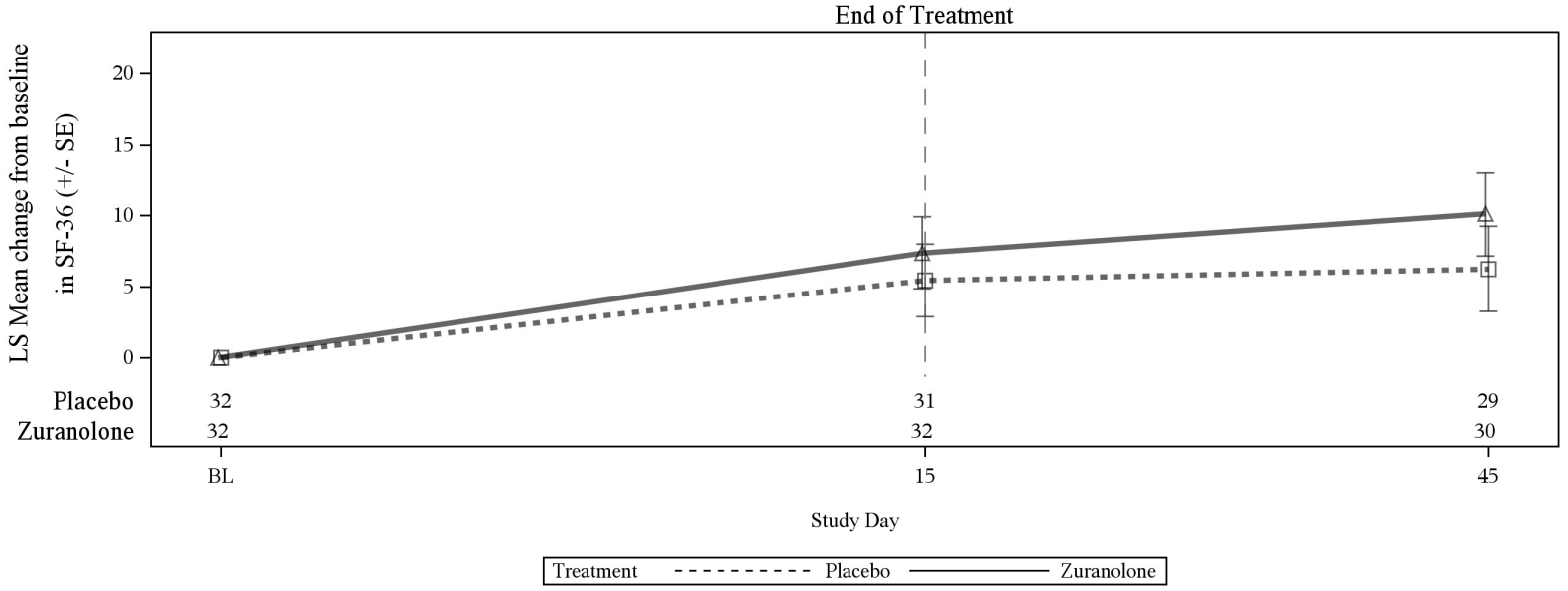
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 12 of 17

Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

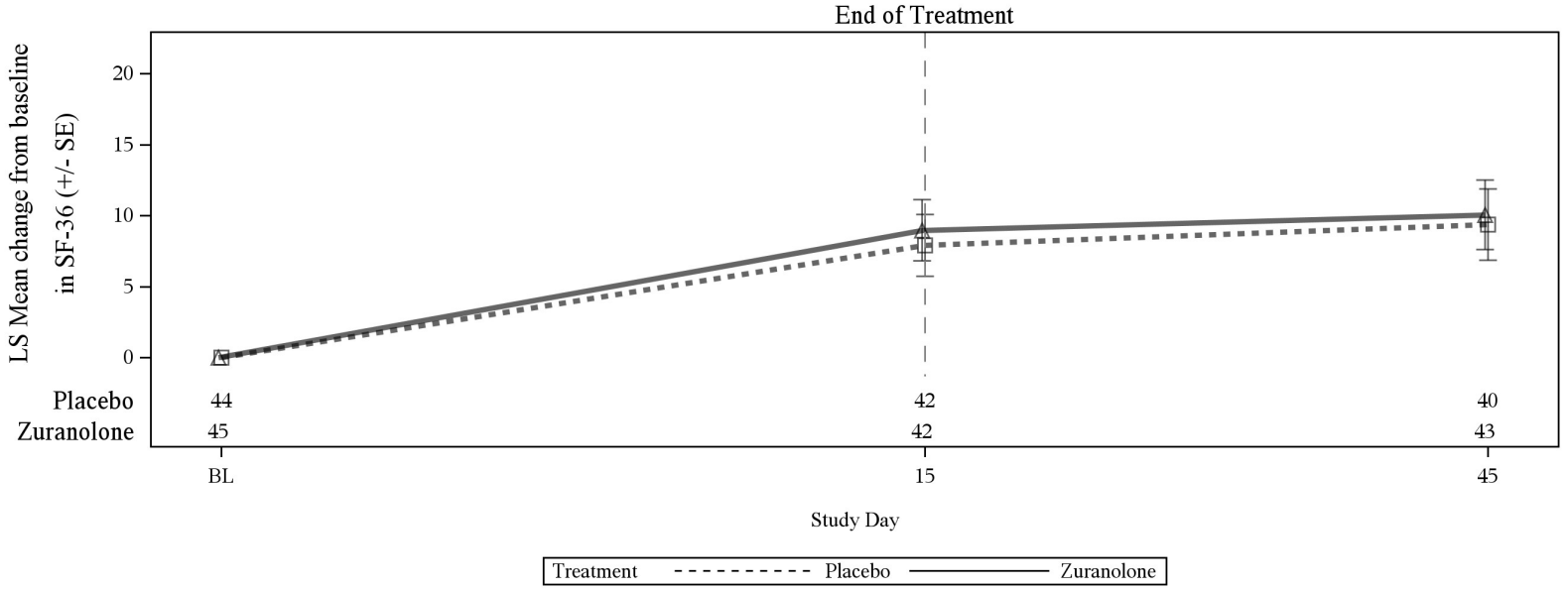
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Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 13 of 17

Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

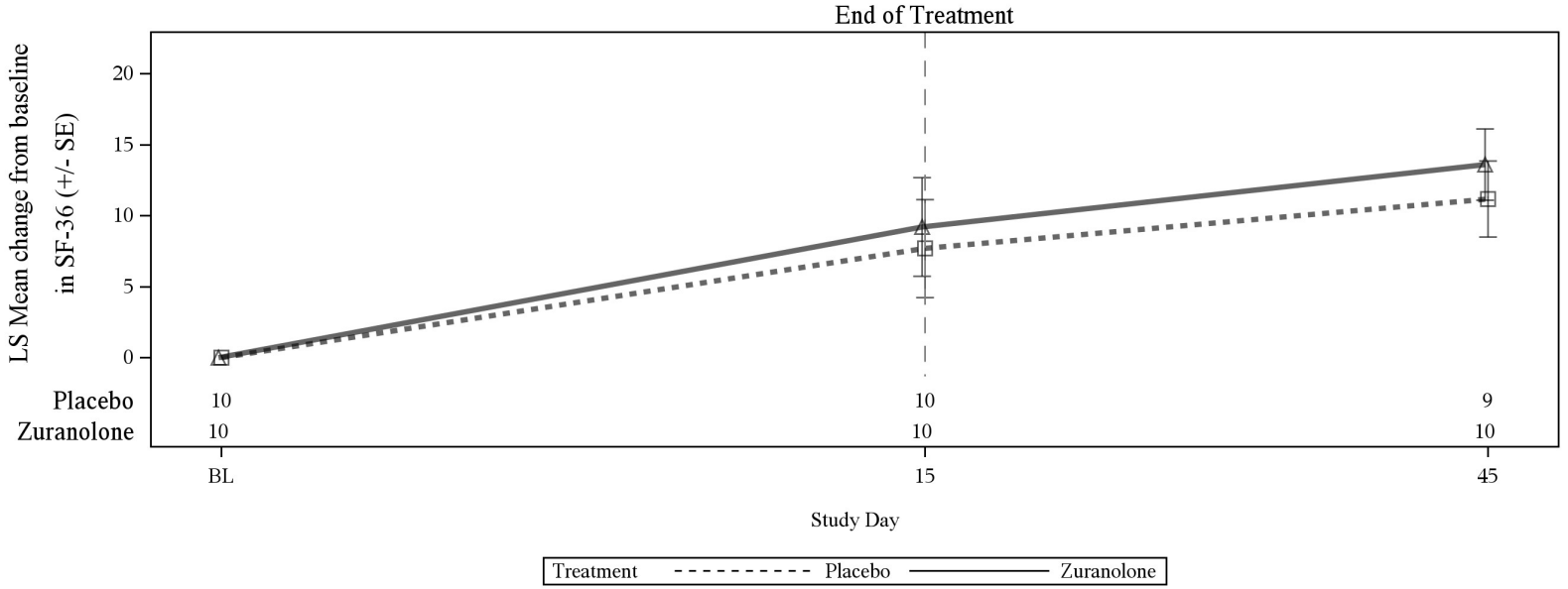
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

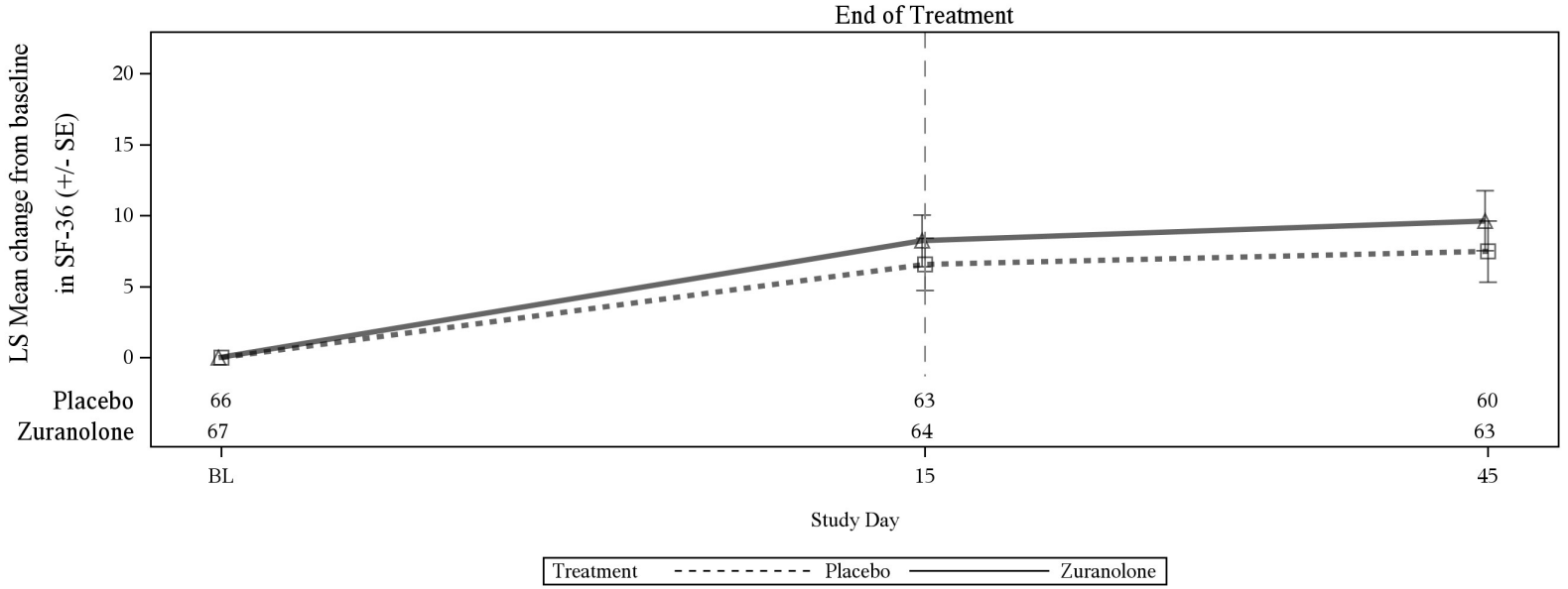
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 15 of 17

Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

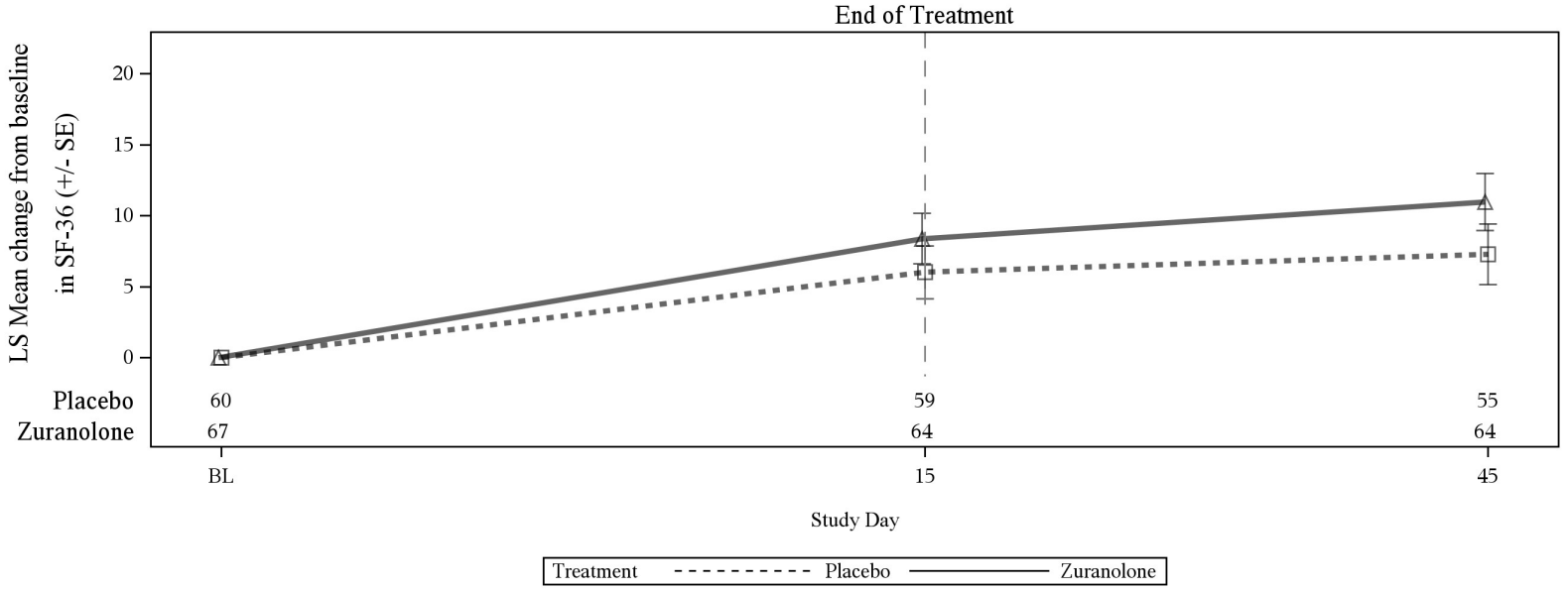
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Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 16 of 17

History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

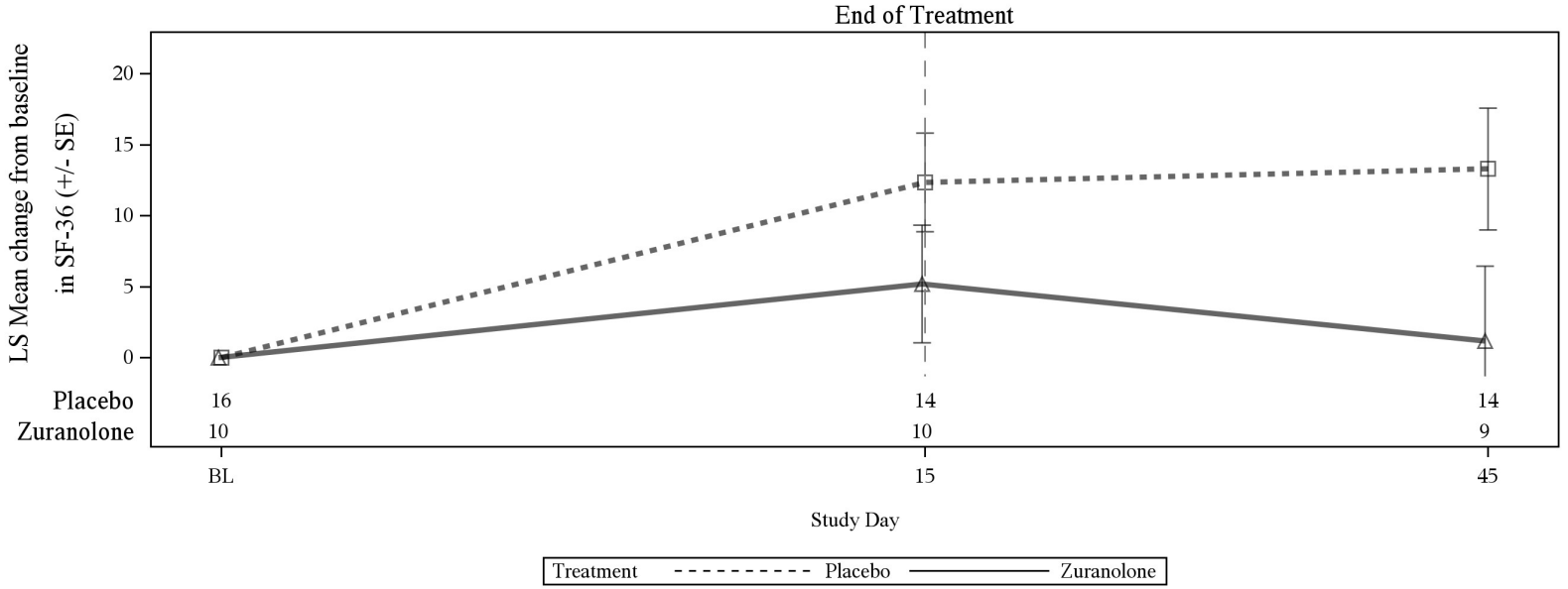
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Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) General Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 17 of 17

History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-gh-mmrm-201-by.sas:f-sf36-gh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

2.6.2 Ansprechen

2.6.2.1 Responder-Analysen

2.6.2.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with a response, n (%) [2]	19 (25.3)	24 (31.6)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.308
95% CI for the RR		(0.821, 2.084)
p-value for RR		0.2593
OR - Odds Ratio (Zuranolone vs. Placebo)		1.424
95% CI for the OR		(0.698, 2.906)
p-value for OR		0.3311
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-ovr.sas:t-sf36-gh-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	22 (29.3)	29 (38.2)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.227
95% CI for the RR		(0.770, 1.957)
p-value for RR		0.3897
OR - Odds Ratio (Zuranolone vs. Placebo)		1.566
95% CI for the OR		(0.759, 3.230)
p-value for OR		0.2252
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-ovr.sas:t-sf36-gh-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.6.2.1 .2 Subgruppen

2.6.2.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	19 (25.3)	24 (31.6)	
Number of subjects with response at Day 45, n (%)	22 (29.3)	29 (38.2)	
Age Group (years)			0.2747
Day 15			
18 - 24, n / N (%)	5/25 (20.0)	3/17 (17.6)	
25 - 45, n / N (%)	14/50 (28.0)	21/59 (35.6)	
Day 45			
18 - 24, n / N (%)	5/25 (20.0)	3/17 (17.6)	
25 - 45, n / N (%)	17/50 (34.0)	26/59 (44.1)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-int.sas:t-sf36-gh-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.6501
Day 15			
<28, n / N (%)	4/22 (18.2)	8/30 (26.7)	
>=28, n / N (%)	15/53 (28.3)	16/46 (34.8)	
Day 45			
<28, n / N (%)	7/22 (31.8)	12/30 (40.0)	
>=28, n / N (%)	15/53 (28.3)	17/46 (37.0)	
Race Group (Black or African American, White)			0.6416
Day 15			
Black or African American, n / N (%)	9/32 (28.1)	9/31 (29.0)	
White, n / N (%)	10/40 (25.0)	15/44 (34.1)	
Day 45			
Black or African American, n / N (%)	10/32 (31.3)	10/31 (32.3)	
White, n / N (%)	12/40 (30.0)	19/44 (43.2)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-int.sas:t-sf36-gh-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.7249
Day 15			
Yes, n / N (%)	2/13 (15.4)	5/16 (31.3)	
No, n / N (%)	17/62 (27.4)	19/60 (31.7)	
Day 45			
Yes, n / N (%)	4/13 (30.8)	6/16 (37.5)	
No, n / N (%)	18/62 (29.0)	23/60 (38.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-int.sas:t-sf36-gh-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.6740(a) 0.3400(b) 0.5369(c)
Day 15			
<=24.9, n / N (%)	6/21 (28.6)	4/13 (30.8)	
25-29.9, n / N (%)	7/20 (35.0)	8/21 (38.1)	
>=30, n / N (%)	6/34 (17.6)	12/42 (28.6)	
Day 45			
<=24.9, n / N (%)	7/21 (33.3)	3/13 (23.1)	
25-29.9, n / N (%)	8/20 (40.0)	10/21 (47.6)	
>=30, n / N (%)	7/34 (20.6)	16/42 (38.1)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.5529
Day 15			
3rd Trimester, n / N (%)	8/32 (25.0)	9/32 (28.1)	
Postpartum, n / N (%)	11/43 (25.6)	15/44 (34.1)	
Day 45			
3rd Trimester, n / N (%)	7/32 (21.9)	13/32 (40.6)	
Postpartum, n / N (%)	15/43 (34.9)	16/44 (36.4)	
Family History of PPD			0.6737
Day 15			
Yes, n / N (%)	2/10 (20.0)	3/10 (30.0)	
No/Unknown, n / N (%)	17/65 (26.2)	21/66 (31.8)	
Day 45			
Yes, n / N (%)	3/10 (30.0)	6/10 (60.0)	
No/Unknown, n / N (%)	19/65 (29.2)	23/66 (34.8)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-int.sas:t-sf36-gh-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.1576
Day 15			
1st Episode, n / N (%)	12/59 (20.3)	22/66 (33.3)	
Recurrent Episode, n / N (%)	7/16 (43.8)	2/10 (20.0)	
Day 45			
1st Episode, n / N (%)	15/59 (25.4)	26/66 (39.4)	
Recurrent Episode, n / N (%)	7/16 (43.8)	3/10 (30.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	2/8 (25.0)	2/10 (20.0)	
>=20, n / N (%)	17/67 (25.4)	22/66 (33.3)	
Day 45			
<20, n / N (%)	3/8 (37.5)	2/10 (20.0)	
>=20, n / N (%)	19/67 (28.4)	27/66 (40.9)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-int.sas:t-sf36-gh-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

2.6.2.1 .2 .2 Subgruppenanalysen

2.6.2.1 .2 .2 .1 Alter

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 15		
Number of subjects with a response, n (%) [2]	5 (20.0)	3 (17.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.88
95% CI for the RR		(0.242, 3.212)
p-value for RR		0.8494
Day 45		
Number of subjects with a response, n (%) [2]	5 (20.0)	3 (17.6)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.88
95% CI for the RR		(0.242, 3.212)
p-value for RR		0.8494

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.
[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 15		
Number of subjects with a response, n (%) [2]	14 (28.0)	21 (35.6)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.27
95% CI for the RR		(0.725, 2.229)
p-value for RR		0.4023
Day 45		
Number of subjects with a response, n (%) [2]	17 (34.0)	26 (44.1)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.30
95% CI for the RR		(0.801, 2.098)
p-value for RR		0.2910

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.6.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 15		
Number of subjects with a response, n (%) [2]	4 (18.2)	8 (26.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.283
95% CI for the RR		(0.454, 3.630)
p-value for RR		0.6384
Day 45		
Number of subjects with a response, n (%) [2]	7 (31.8)	12 (40.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.100
95% CI for the RR		(0.526, 2.300)
p-value for RR		0.8003

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 15		
Number of subjects with a response, n (%) [2]	15 (28.3)	16 (34.8)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.362
95% CI for the RR		(0.795, 2.333)
p-value for RR		0.2612
Day 45		
Number of subjects with a response, n (%) [2]	15 (28.3)	17 (37.0)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.447
95% CI for the RR		(0.815, 2.569)
p-value for RR		0.2073

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.6.2.1 .2 .2 .3 Abstammung

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 15		
Number of subjects with a response, n (%) [2]	9 (28.1)	9 (29.0)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.03
95% CI for the RR		(0.473, 2.254)
p-value for RR		0.9365
Day 45		
Number of subjects with a response, n (%) [2]	10 (31.3)	10 (32.3)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.03
95% CI for the RR		(0.500, 2.129)
p-value for RR		0.9315

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 15		
Number of subjects with a response, n (%) [2]	10 (25.0)	15 (34.1)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.36
95% CI for the RR		(0.694, 2.681)
p-value for RR		0.3685
Day 45		
Number of subjects with a response, n (%) [2]	12 (30.0)	19 (43.2)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.44
95% CI for the RR		(0.804, 2.576)
p-value for RR		0.2201

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.6.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 15		
Number of subjects with a response, n (%) [2]	2 (15.4)	5 (31.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.964
95% CI for the RR		(0.478, 8.065)
p-value for RR		0.3489
Day 45		
Number of subjects with a response, n (%) [2]	4 (30.8)	6 (37.5)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.178
95% CI for the RR		(0.426, 3.263)
p-value for RR		0.7520

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 General Health subscale total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 15		
Number of subjects with a response, n (%) [2]	17 (27.4)	19 (31.7)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.168
95% CI for the RR		(0.698, 1.954)
p-value for RR		0.5554
Day 45		
Number of subjects with a response, n (%) [2]	18 (29.0)	23 (38.3)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.335
95% CI for the RR		(0.809, 2.203)
p-value for RR		0.2587

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 General Health subscale total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.6.2.1 .2 .2 .5 BMI

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 15		
Number of subjects with a response, n (%) [2]	6 (28.6)	4 (30.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.305
95% CI for the RR		(0.500, 3.406)
p-value for RR		0.5864
Day 45		
Number of subjects with a response, n (%) [2]	7 (33.3)	3 (23.1)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.839
95% CI for the RR		(0.242, 2.911)
p-value for RR		0.7821

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 15		
Number of subjects with a response, n (%) [2]	7 (35.0)	8 (38.1)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.171
95% CI for the RR		(0.535, 2.567)
p-value for RR		0.6927
Day 45		
Number of subjects with a response, n (%) [2]	8 (40.0)	10 (47.6)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.281
95% CI for the RR		(0.661, 2.482)
p-value for RR		0.4626

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 15		
Number of subjects with a response, n (%) [2]	6 (17.6)	12 (28.6)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.584
95% CI for the RR		(0.672, 3.733)
p-value for RR		0.2929
Day 45		
Number of subjects with a response, n (%) [2]	7 (20.6)	16 (38.1)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.810
95% CI for the RR		(0.841, 3.899)
p-value for RR		0.1294

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.6.2.1 .2 .2 .6 Beginn der PPD

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 15		
Number of subjects with a response, n (%) [2]	8 (25.0)	9 (28.1)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.197
95% CI for the RR		(0.534, 2.686)
p-value for RR		0.6620
Day 45		
Number of subjects with a response, n (%) [2]	7 (21.9)	13 (40.6)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.855
95% CI for the RR		(0.846, 4.068)
p-value for RR		0.1229

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 15		
Number of subjects with a response, n (%) [2]	11 (25.6)	15 (34.1)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.290
95% CI for the RR		(0.730, 2.280)
p-value for RR		0.3798
Day 45		
Number of subjects with a response, n (%) [2]	15 (34.9)	16 (36.4)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.934
95% CI for the RR		(0.515, 1.696)
p-value for RR		0.8236

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.6.2.1 .2 .2 .7 PPD in der Familie

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 15		
Number of subjects with a response, n (%) [2]	2 (20.0)	3 (30.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.338
95% CI for the RR		(0.324, 5.526)
p-value for RR		0.6872
Day 45		
Number of subjects with a response, n (%) [2]	3 (30.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.784
95% CI for the RR		(0.612, 5.205)
p-value for RR		0.2891

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 15		
Number of subjects with a response, n (%) [2]	17 (26.2)	21 (31.8)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.252
95% CI for the RR		(0.759, 2.065)
p-value for RR		0.3781
Day 45		
Number of subjects with a response, n (%) [2]	19 (29.2)	23 (34.8)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.227
95% CI for the RR		(0.743, 2.027)
p-value for RR		0.4241

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.6.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 15		
Number of subjects with a response, n (%) [2]	12 (20.3)	22 (33.3)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.579
95% CI for the RR		(0.893, 2.791)
p-value for RR		0.1161
Day 45		
Number of subjects with a response, n (%) [2]	15 (25.4)	26 (39.4)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.493
95% CI for the RR		(0.882, 2.528)
p-value for RR		0.1360

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 15		
Number of subjects with a response, n (%) [2]	7 (43.8)	2 (20.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.346
95% CI for the RR		(0.123, 0.976)
p-value for RR		0.0448
Day 45		
Number of subjects with a response, n (%) [2]	7 (43.8)	3 (30.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.520
95% CI for the RR		(0.196, 1.380)
p-value for RR		0.1888

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

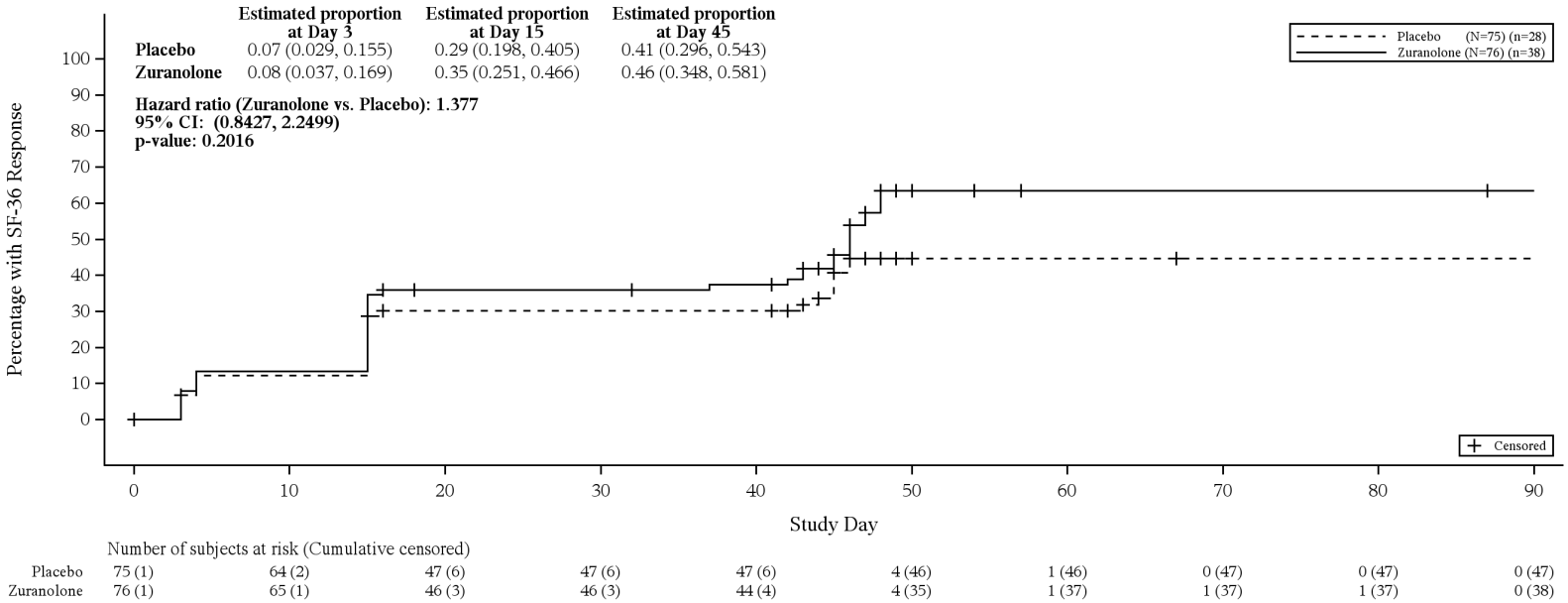
Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-201-by.sas:t-sf36-gh-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.6.2.2 TTE-Analysen

2.6.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-ovr.sas:f-sf36-gh-resp15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	28 (37.3)	38 (50.0)
Time to first SF-36 General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (15.0 , 45.0)	15.0 (NE, NE)
50th percentile - median (95% CI)	NE (45.0, NE)	46.0 (42.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.377
95% CI for the HR		(0.8427 , 2.2499)
p-value for the HR		0.2016

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-ovr.sas:t-sf36-gh-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.6.2.2 .2 Subgruppen

2.6.2.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	28 (37.3)	38 (50.0)	
Age Group (years)			
18 - 24, n / N (%)	8/25 (32.0)	5/17 (29.4)	0.1314
25 - 45, n / N (%)	20/50 (40.0)	33/59 (55.9)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	8/22 (36.4)	12/30 (40.0)	0.3409
>=28, n / N (%)	20/53 (37.7)	26/46 (56.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	13/32 (40.6)	15/31 (48.4)	0.8864
White, n / N (%)	15/40 (37.5)	23/44 (52.3)	
Antidepressant Use at Baseline			
Yes, n / N (%)	5/13 (38.5)	7/16 (43.8)	0.9374
No, n / N (%)	23/62 (37.1)	31/60 (51.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-int.sas:t-sf36-gh-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	9/21 (42.9)	5/13 (38.5)	0.7496(a)
25-29.9, n / N (%)	11/20 (55.0)	11/21 (52.4)	0.2413(b)
>=30, n / N (%)	8/34 (23.5)	22/42 (52.4)	0.3213(c)
Onset of PPD			
3rd Trimester, n / N (%)	10/32 (31.3)	16/32 (50.0)	0.4297
Postpartum, n / N (%)	18/43 (41.9)	22/44 (50.0)	
Family History of PPD			
Yes, n / N (%)	4/10 (40.0)	7/10 (70.0)	0.7834
No/Unknown, n / N (%)	24/65 (36.9)	31/66 (47.0)	
History of PPD			
1st Episode, n / N (%)	20/59 (33.9)	35/66 (53.0)	0.1499
Recurrent Episode, n / N (%)	8/16 (50.0)	3/10 (30.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	3/8 (37.5)	2/10 (20.0)	NA
>=20, n / N (%)	25/67 (37.3)	36/66 (54.5)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-int.sas:t-sf36-gh-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.6.2.2 .2 .2 Subgruppenanalysen

2.6.2.2 .2 .2 .1 Alter

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	8 (32.0)	5 (29.4)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0, NE)	42.0 (3.0, NE)
50th percentile - median (95% CI)	NE (44.0, NE)	NE (16.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.615
95% CI for the HR		(0.1977 , 1.9151)
p-value for the HR		0.4019

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	20 (40.0)	33 (55.9)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (15.0 , 45.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	46.0 (45.0, NE)	45.0 (15.0 , 47.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	48.0 (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.616
95% CI for the HR		(0.9150 , 2.8550)
p-value for the HR		0.0981

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.6.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	8 (36.4)	12 (40.0)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	43.0 (3.0, NE)	15.0 (3.0 , 46.0)
50th percentile - median (95% CI)	NE (43.0, NE)	47.0 (42.0, NE)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	NE (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.870
95% CI for the HR		(0.3481 , 2.1743)
p-value for the HR		0.7657

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	20 (37.7)	26 (56.5)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (15.0 , 45.0)	15.0 (NE, NE)
50th percentile - median (95% CI)	NE (45.0, NE)	45.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.648
95% CI for the HR		(0.9119 , 2.9778)
p-value for the HR		0.0980

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.6.2.2 .2 .2 .3 Abstammung

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	13 (40.6)	15 (48.4)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (15.0 , 44.0)	15.0 (4.0 , 46.0)
50th percentile - median (95% CI)	NE (16.0, NE)	46.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.136
95% CI for the HR		(0.5351 , 2.4117)
p-value for the HR		0.7399

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	15 (37.5)	23 (52.3)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 46.0)	15.0 (4.0 , 37.0)
50th percentile - median (95% CI)	NE (45.0, NE)	45.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.352
95% CI for the HR		(0.7032 , 2.5990)
p-value for the HR		0.3660

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.6.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	5 (38.5)	7 (43.8)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	45.0 (3.0, NE)	15.0 (3.0 , 43.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	NE (15.0, NE)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.364
95% CI for the HR		(0.4265 , 4.3655)
p-value for the HR		0.6004

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	23 (37.1)	31 (51.7)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (15.0 , 45.0)	15.0 (4.0 , 16.0)
50th percentile - median (95% CI)	NE (45.0, NE)	46.0 (16.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.368
95% CI for the HR		(0.7948 , 2.3535)
p-value for the HR		0.2582

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.6.2.2 .2 .2 .5 BMI

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	9 (42.9)	5 (38.5)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 45.0)	16.0 (3.0, NE)
50th percentile - median (95% CI)	45.0 (15.0, NE)	46.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	NE (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.089
95% CI for the HR		(0.3343 , 3.5481)
p-value for the HR		0.8874

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	11 (55.0)	11 (52.4)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 16.0)	15.0 (3.0 , 37.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	45.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	NE (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.141
95% CI for the HR		(0.4774 , 2.7288)
p-value for the HR		0.7662

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	8 (23.5)	22 (52.4)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	45.0 (15.0, NE)	15.0 (4.0 , 42.0)
50th percentile - median (95% CI)	NE (NE, NE)	46.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.079
95% CI for the HR		(0.9189 , 4.7057)
p-value for the HR		0.0789

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.6.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	10 (31.3)	16 (50.0)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0, NE)	15.0 (4.0 , 43.0)
50th percentile - median (95% CI)	NE (45.0, NE)	46.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.643
95% CI for the HR		(0.7380 , 3.6573)
p-value for the HR		0.2240

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	18 (41.9)	22 (50.0)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 45.0)	15.0 (4.0 , 42.0)
50th percentile - median (95% CI)	46.0 (43.0, NE)	46.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.185
95% CI for the HR		(0.6338 , 2.2145)
p-value for the HR		0.5953

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.6.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	4 (40.0)	7 (70.0)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	45.0 (15.0, NE)	15.0 (15.0 , 46.0)
50th percentile - median (95% CI)	NE (15.0, NE)	44.5 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	48.0 (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.233
95% CI for the HR		(0.3098 , 4.9034)
p-value for the HR		0.7666

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	24 (36.9)	31 (47.0)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 44.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	NE (45.0, NE)	46.0 (37.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.339
95% CI for the HR		(0.7807 , 2.2961)
p-value for the HR		0.2890

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.6.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	20 (33.9)	35 (53.0)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	16.0 (4.0 , 46.0)	15.0 (NE, NE)
50th percentile - median (95% CI)	NE (45.0, NE)	46.0 (16.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.604
95% CI for the HR		(0.9245 , 2.7833)
p-value for the HR		0.0928

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-resp15-tte-201-by.sas:t-sf36-gh-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	8 (50.0)	3 (30.0)
Time to first General Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 15.0)	48.0 (3.0, NE)
50th percentile - median (95% CI)	30.0 (15.0, NE)	NE (3.0, NE)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.211
95% CI for the HR		(0.0384 , 1.1621)
p-value for the HR		0.0739

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

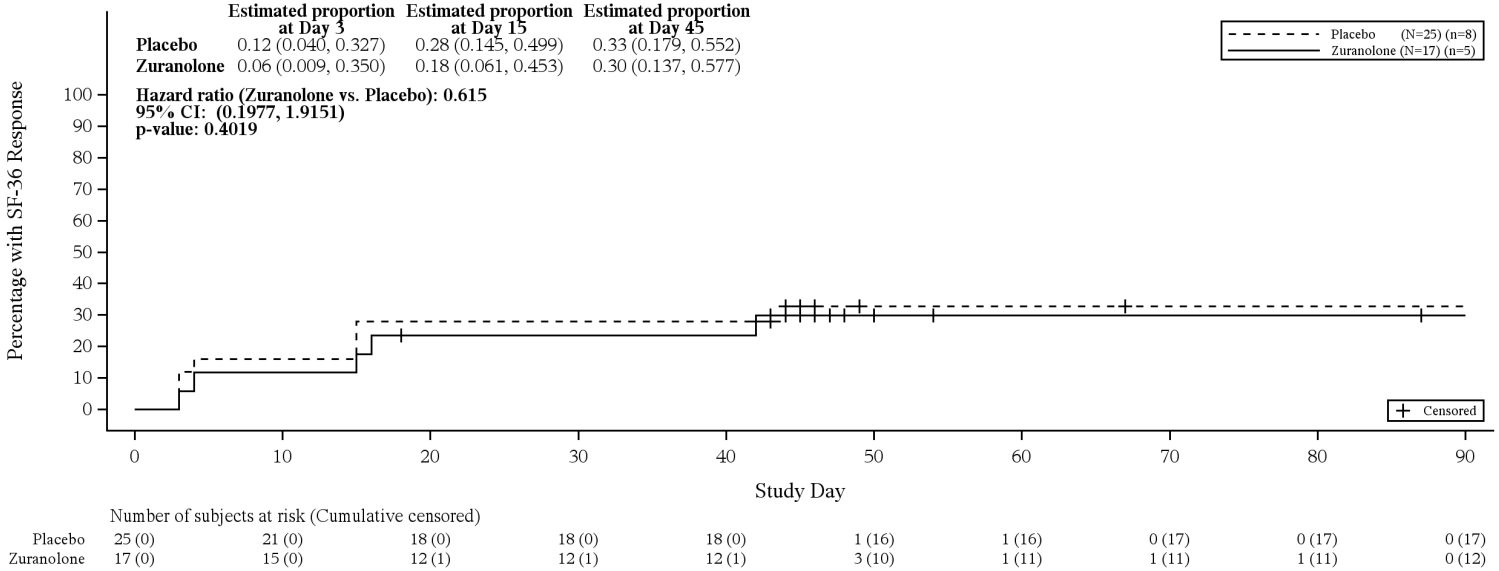
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2.6.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

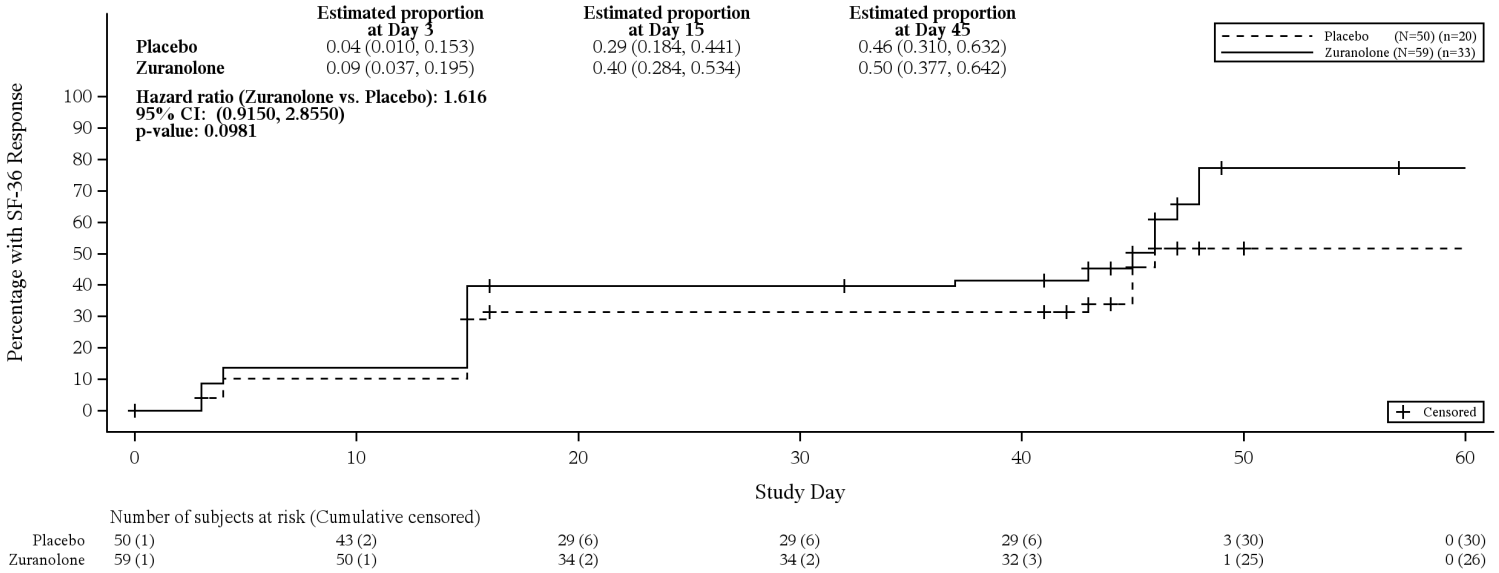
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

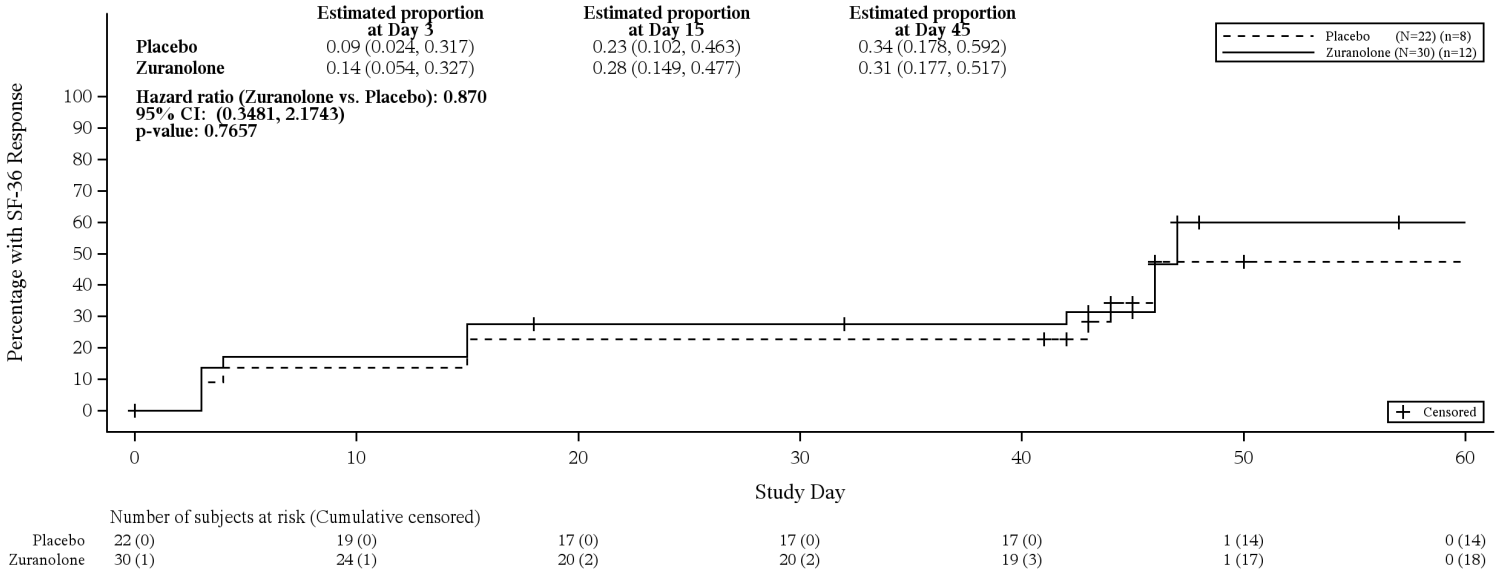
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

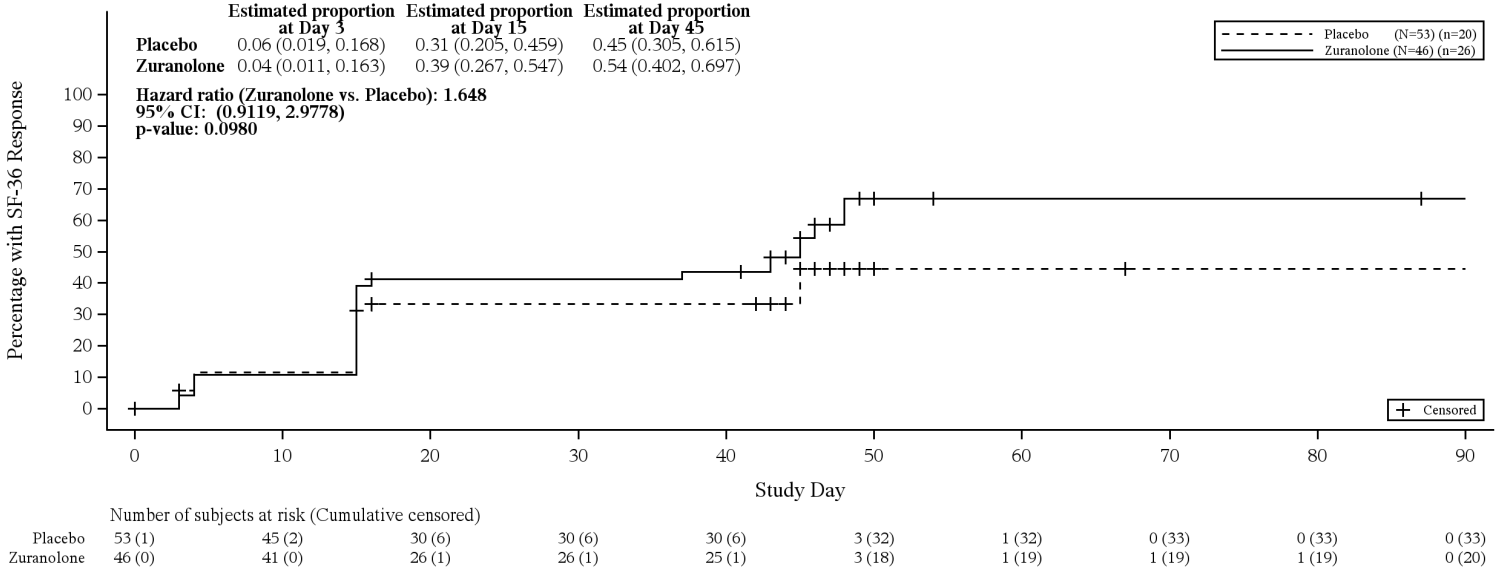
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

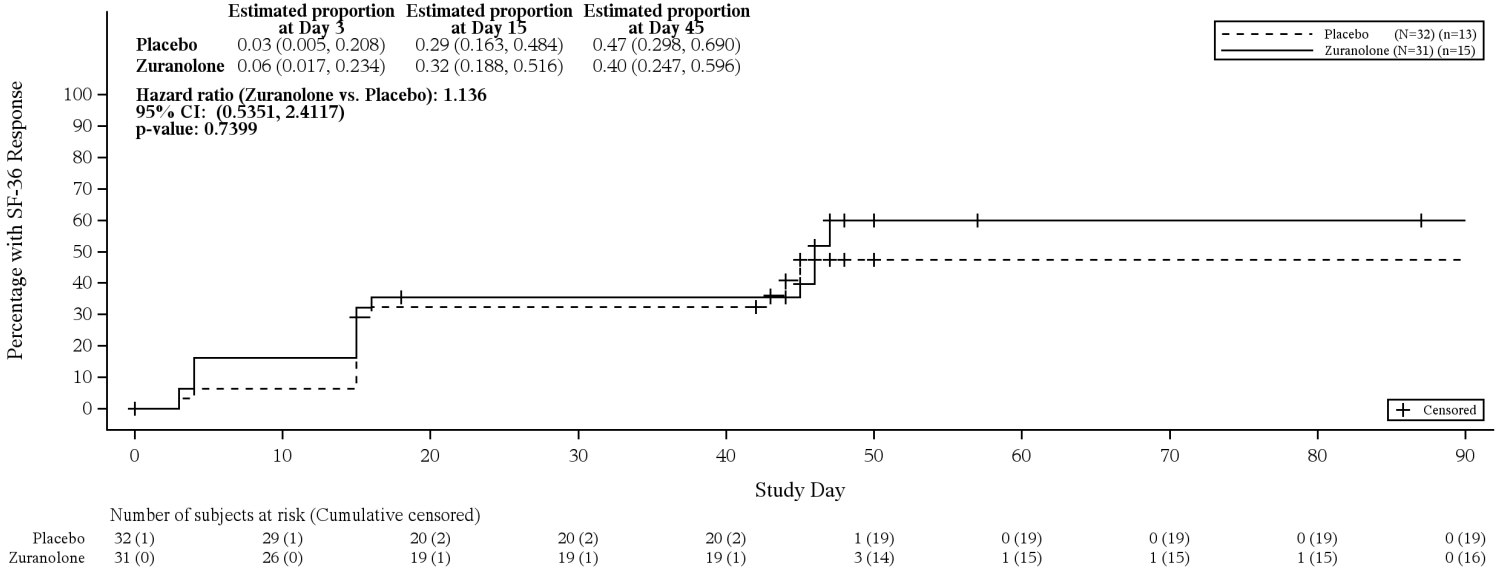
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

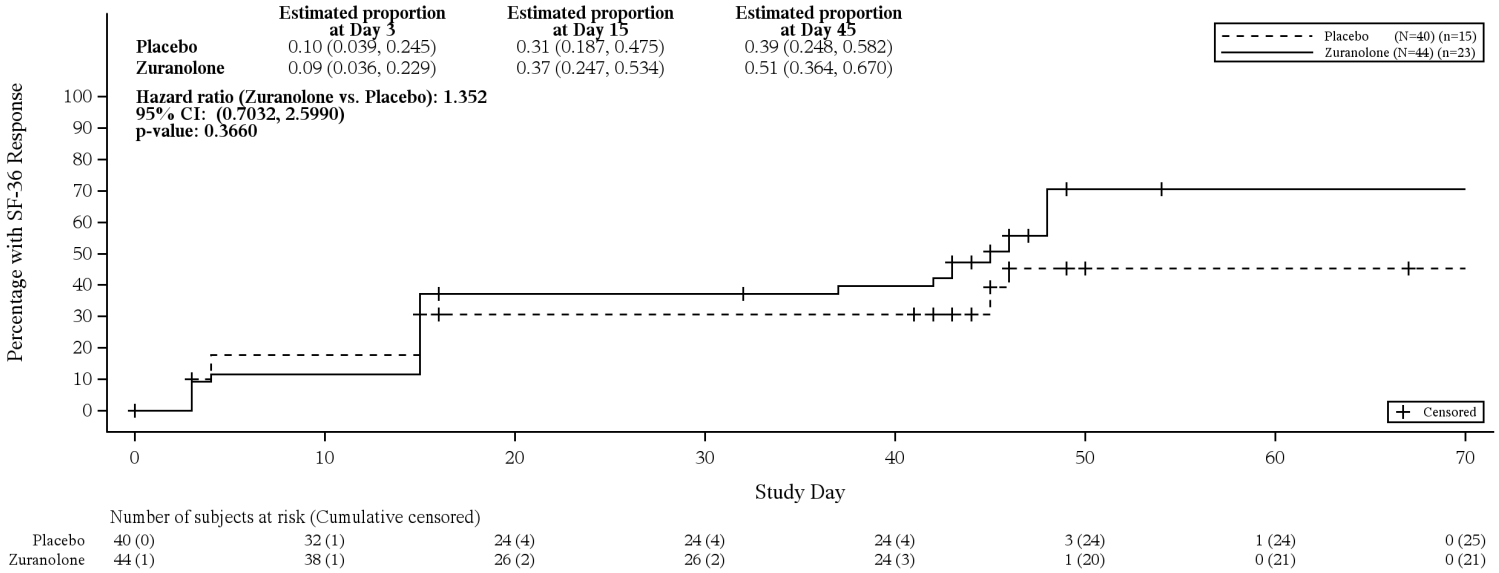
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

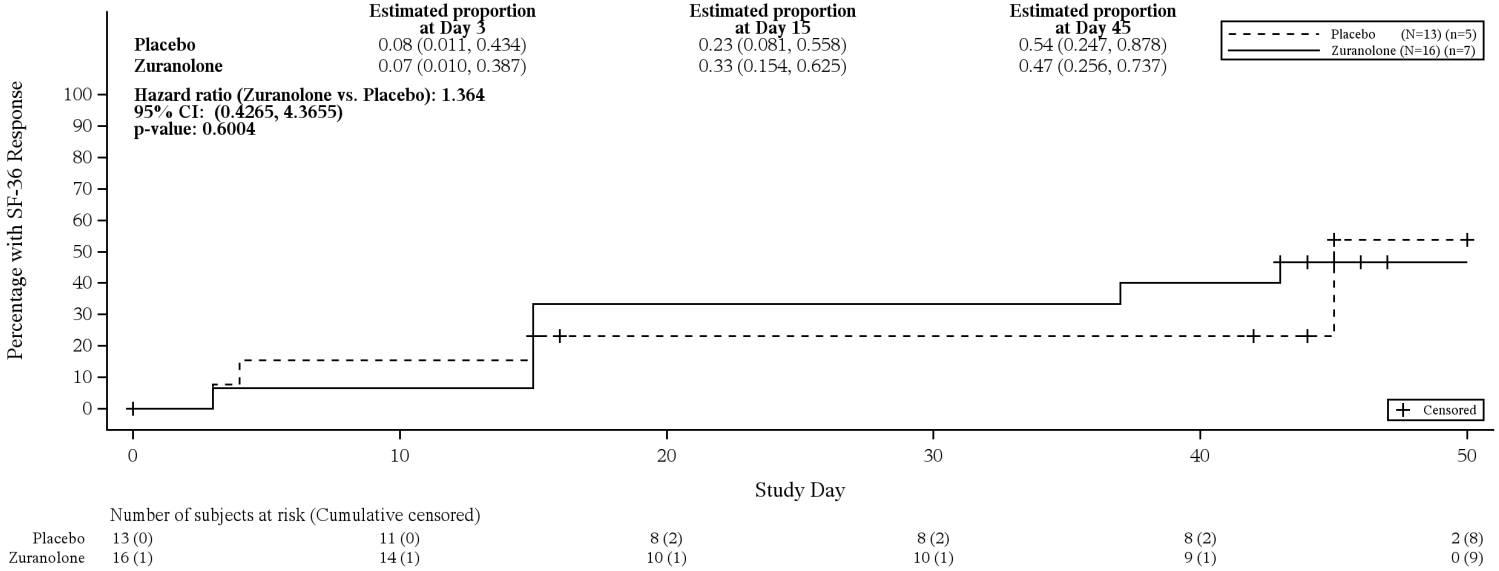
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	13 (0)	11 (0)	8 (2)	8 (2)	8 (2)	2 (8)
Zuranolone	16 (1)	14 (1)	10 (1)	10 (1)	9 (1)	0 (9)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

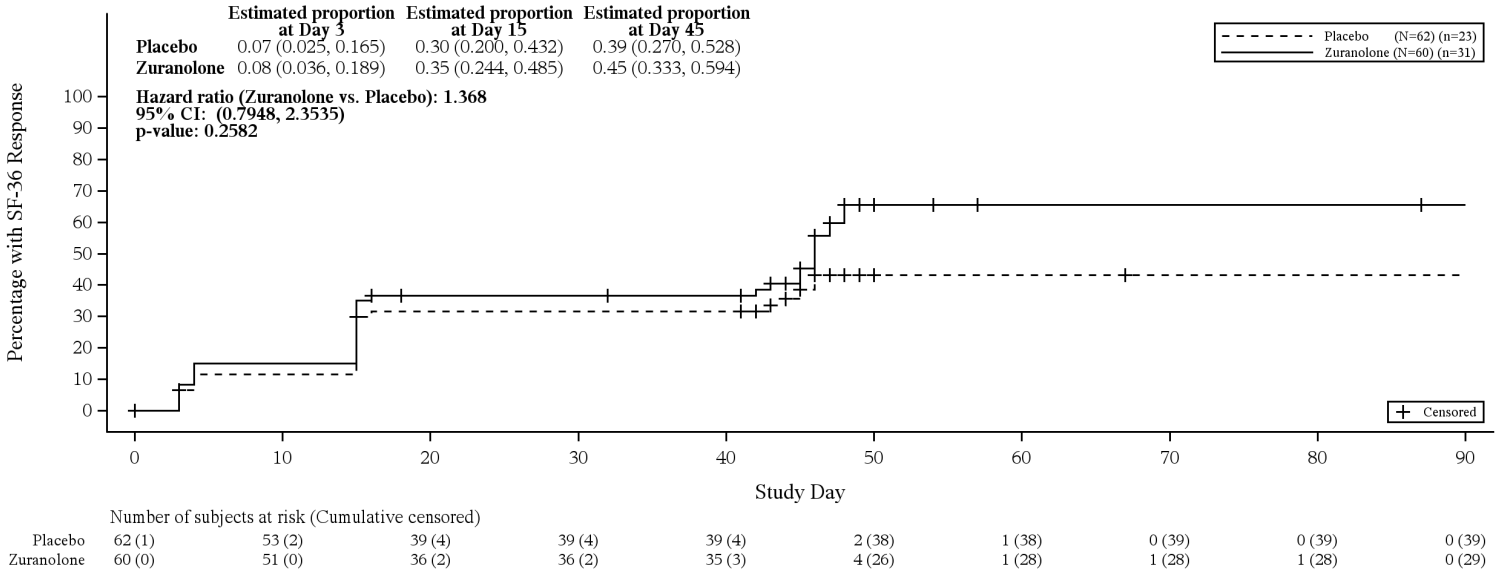
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

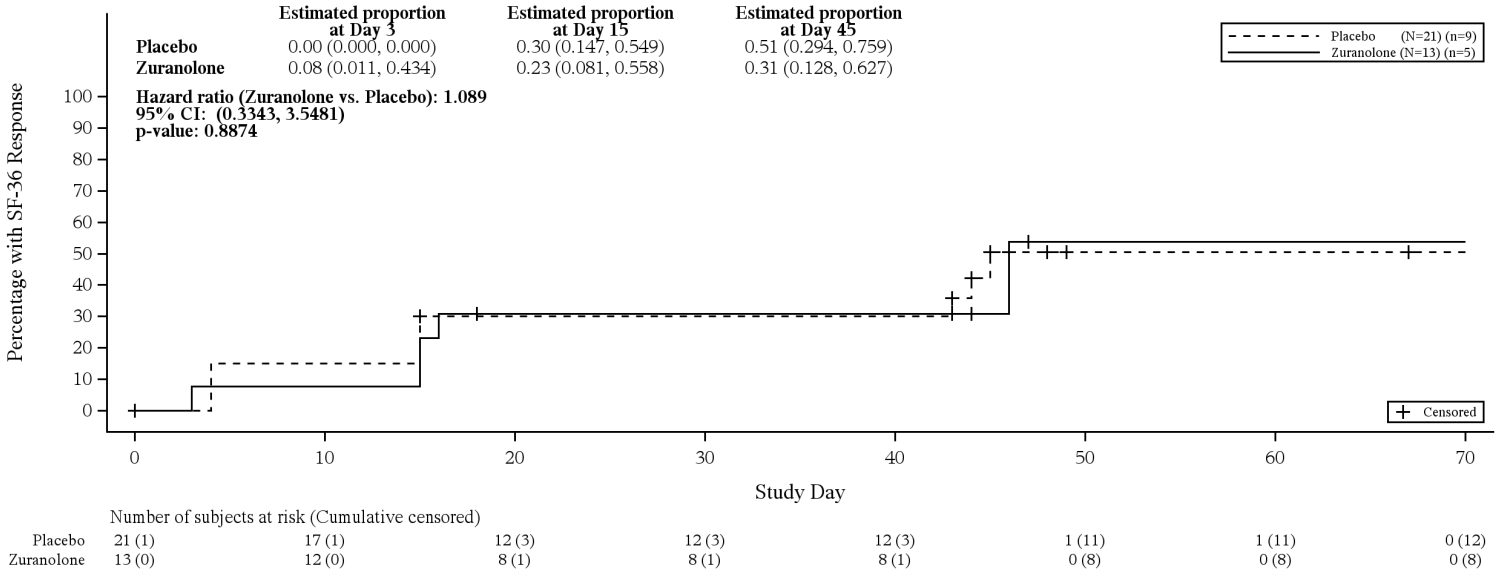
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

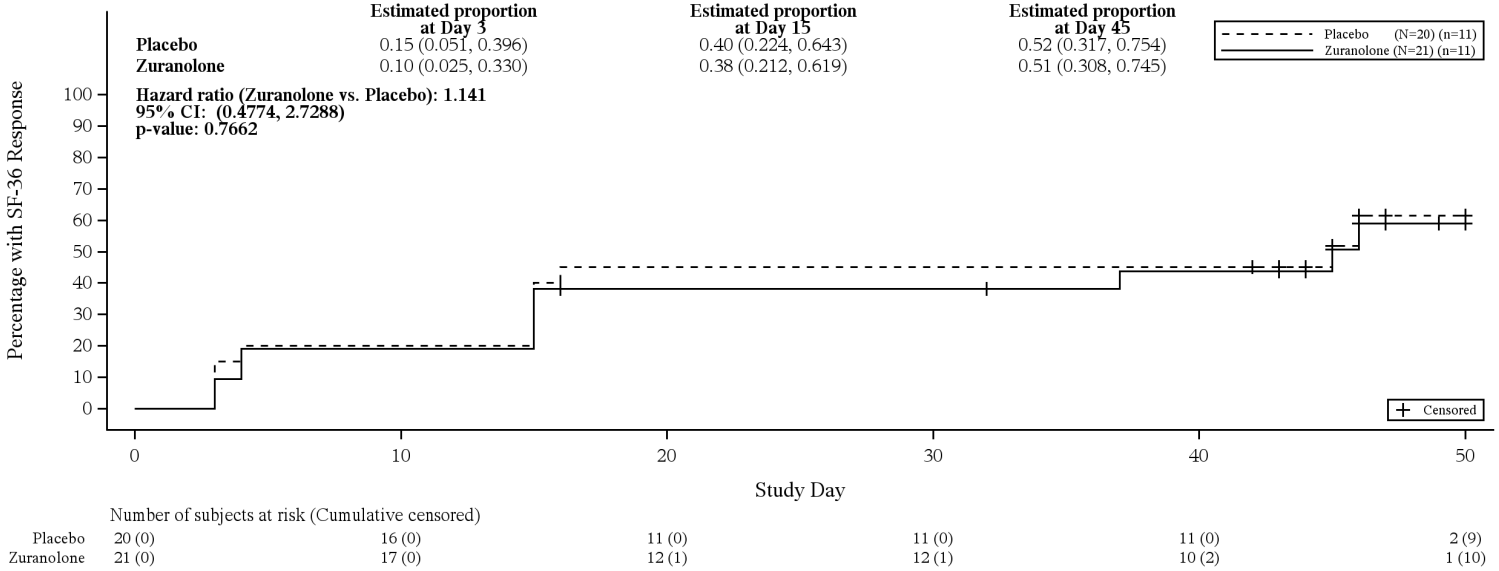
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Number of subjects at risk (Cumulative censored)

Placebo	20 (0)	16 (0)	11 (0)	11 (0)	11 (0)	2 (9)
Zuranolone	21 (0)	17 (0)	12 (1)	12 (1)	10 (2)	1 (10)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

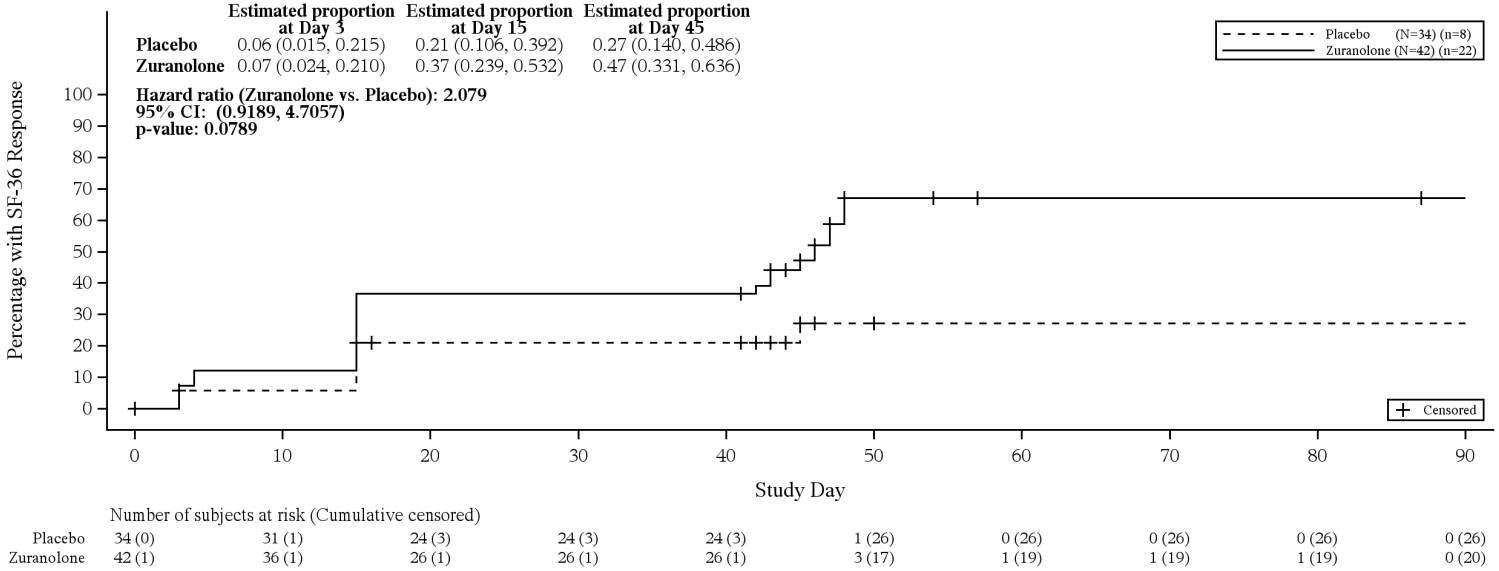
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

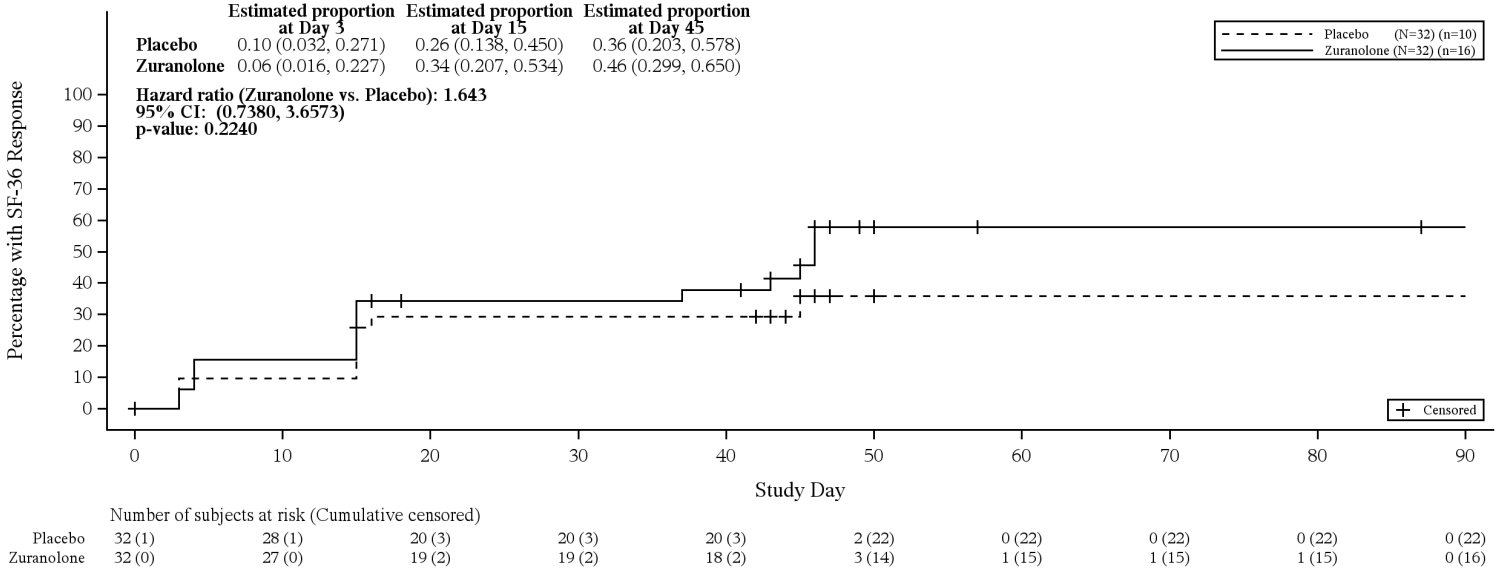
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

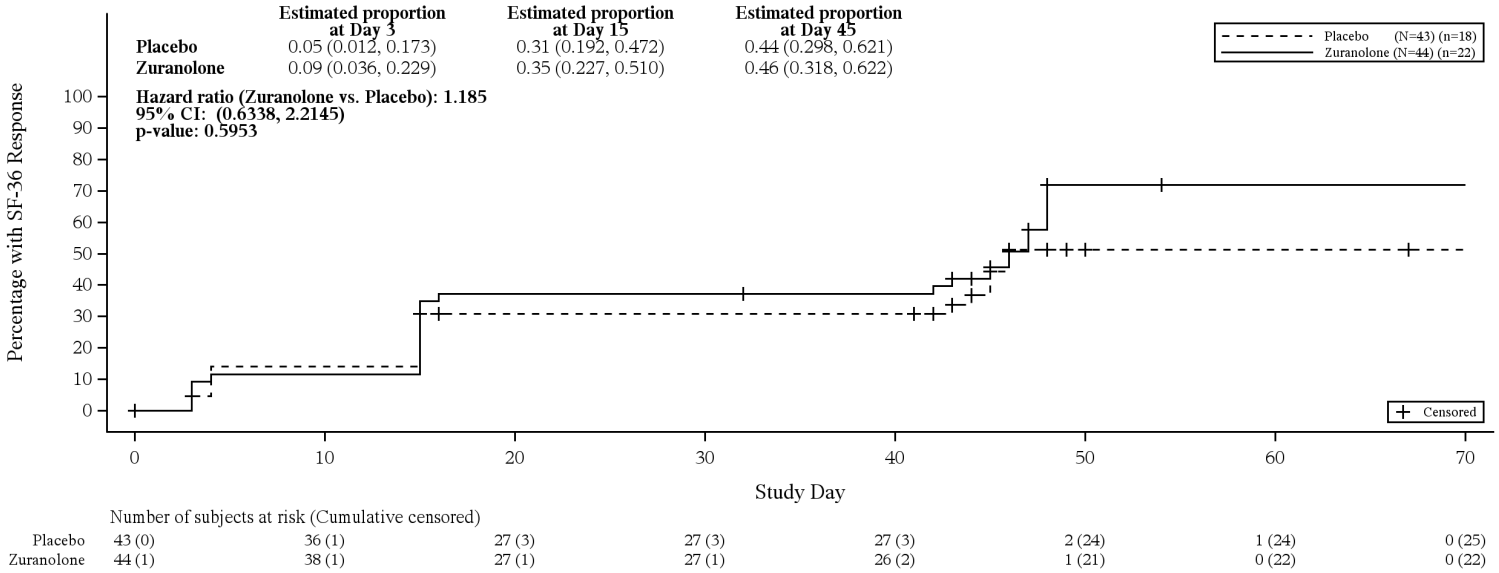
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

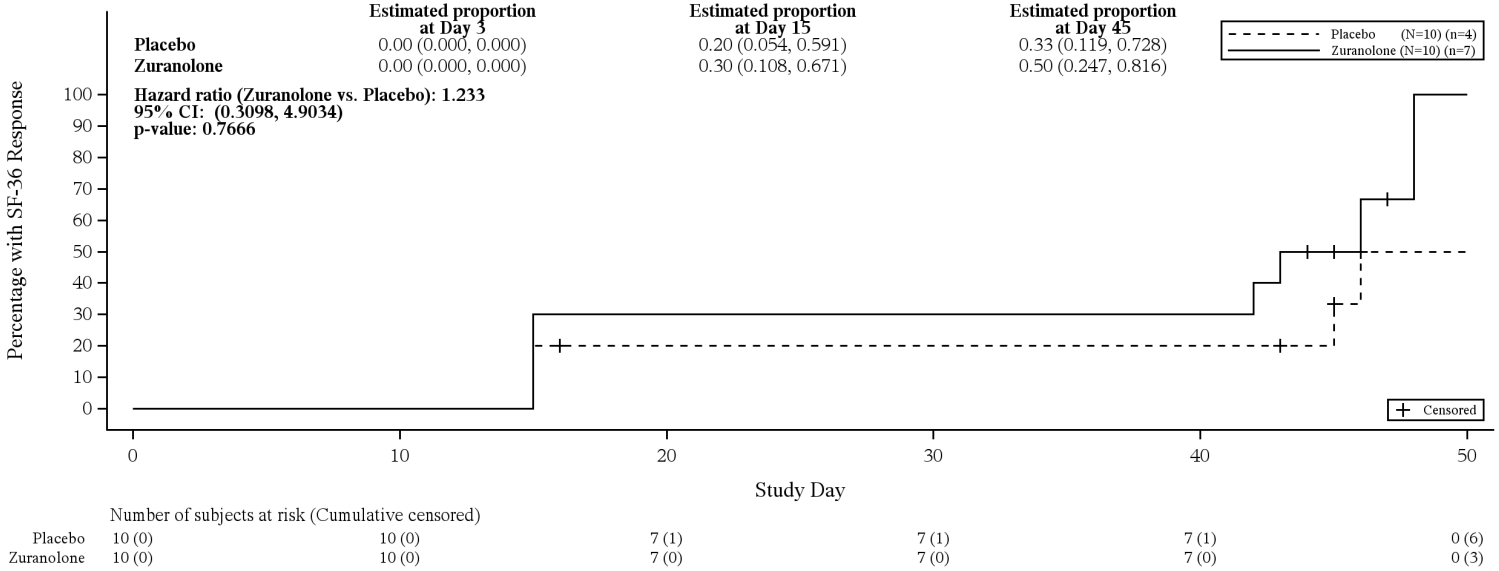
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Number of subjects at risk (Cumulative censored)

Placebo	10 (0)	10 (0)	7 (1)	7 (1)	7 (1)	0 (6)
Zuranolone	10 (0)	10 (0)	7 (0)	7 (0)	7 (0)	0 (3)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

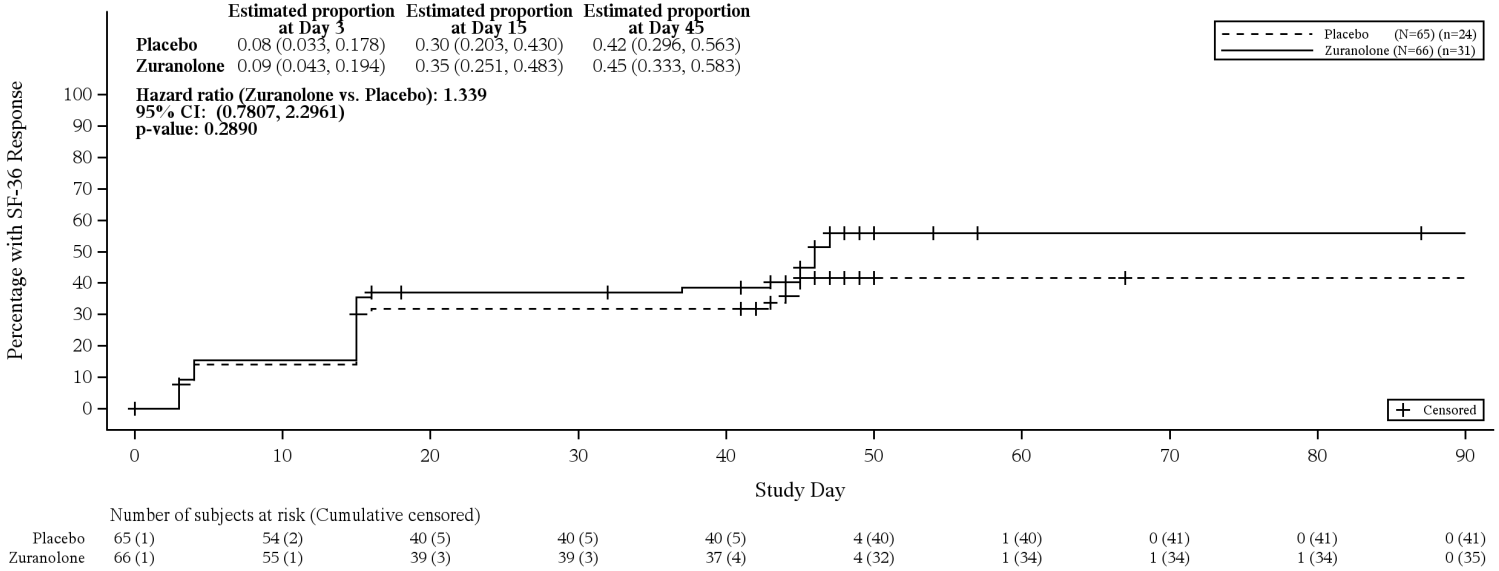
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

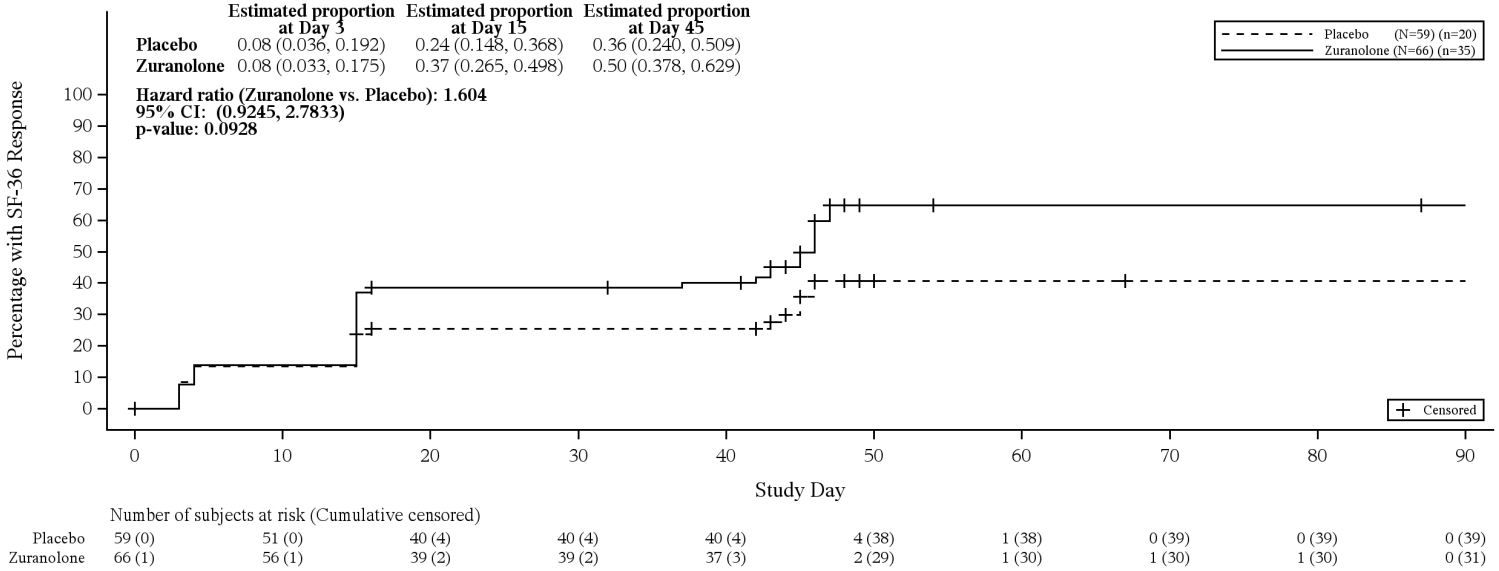
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

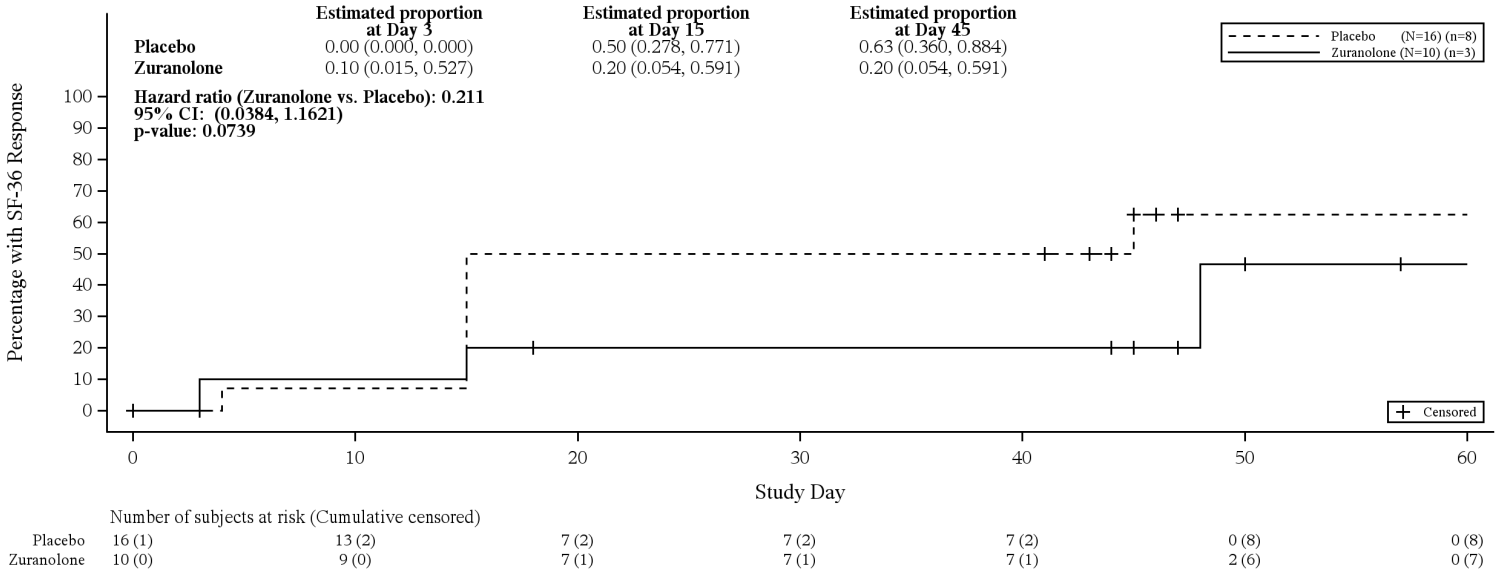
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-gh-resp15-tte-201-by.sas:f-sf36-gh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

2.6.3 Verschlechterung

2.6.3.1 Responder-Analysen

2.6.3.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) General Health Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with worsening, n (%) [2]	5 (6.7)	2 (2.6)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.402
95% CI for the RR		(0.080, 2.021)
p-value for RR		0.2684
OR - Odds Ratio (Zuranolone vs. Placebo)		0.376
95% CI for the OR		(0.068, 2.091)
p-value for OR		0.2639
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.
[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 General Health subscale score worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-gh-wors15-201-ovr.sas:t-sf36-gh-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	3 (4.0)	5 (6.6)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.673
95% CI for the RR		(0.428, 6.538)
p-value for RR		0.4593
OR - Odds Ratio (Zuranolone vs. Placebo)		1.744
95% CI for the OR		(0.401, 7.581)
p-value for OR		0.4580
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 General Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing SF-36 General Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 General Health subscale score worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-gh-wors15-201-ovr.sas:t-sf36-gh-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.6.3.1 .2 Subgruppen

2.6.3.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) General Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	5 (6.7)	2 (2.6)	
Number of subjects with response at Day 45, n (%)	3 (4.0)	5 (6.6)	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	1/25 (4.0)	0/17	
25 - 45, n / N (%)	4/50 (8.0)	2/59 (3.4)	
Day 45			
18 - 24, n / N (%)	2/25 (8.0)	3/17 (17.6)	
25 - 45, n / N (%)	1/50 (2.0)	2/59 (3.4)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-wors15-201-int.sas:t-sf36-gh-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	1/22 (4.5)	2/30 (6.7)	
>=28, n / N (%)	4/53 (7.5)	0/46	
Day 45			
<28, n / N (%)	1/22 (4.5)	2/30 (6.7)	
>=28, n / N (%)	2/53 (3.8)	3/46 (6.5)	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	2/32 (6.3)	2/31 (6.5)	
White, n / N (%)	3/40 (7.5)	0/44	
Day 45			
Black or African American, n / N (%)	0/32	3/31 (9.7)	
White, n / N (%)	3/40 (7.5)	2/44 (4.5)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-wors15-201-int.sas:t-sf36-gh-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	5/62 (8.1)	2/60 (3.3)	
Day 45			
Yes, n / N (%)	1/13 (7.7)	2/16 (12.5)	
No, n / N (%)	2/62 (3.2)	3/60 (5.0)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-wors15-201-int.sas:t-sf36-gh-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	1/21 (4.8)	0/13	
25-29.9, n / N (%)	1/20 (5.0)	1/21 (4.8)	
>=30, n / N (%)	3/34 (8.8)	1/42 (2.4)	
Day 45			
<=24.9, n / N (%)	1/21 (4.8)	1/13 (7.7)	
25-29.9, n / N (%)	1/20 (5.0)	1/21 (4.8)	
>=30, n / N (%)	1/34 (2.9)	3/42 (7.1)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-wors15-201-int.sas:t-sf36-gh-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	2/32 (6.3)	1/32 (3.1)	
Postpartum, n / N (%)	3/43 (7.0)	1/44 (2.3)	
Day 45			
3rd Trimester, n / N (%)	1/32 (3.1)	3/32 (9.4)	
Postpartum, n / N (%)	2/43 (4.7)	2/44 (4.5)	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	5/65 (7.7)	2/66 (3.0)	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	3/65 (4.6)	5/66 (7.6)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-wors15-201-int.sas:t-sf36-gh-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) General Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	4/59 (6.8)	2/66 (3.0)	
Recurrent Episode, n / N (%)	1/16 (6.3)	0/10	
Day 45			
1st Episode, n / N (%)	2/59 (3.4)	3/66 (4.5)	
Recurrent Episode, n / N (%)	1/16 (6.3)	2/10 (20.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	1/8 (12.5)	1/10 (10.0)	
>=20, n / N (%)	4/67 (6.0)	1/66 (1.5)	
Day 45			
<20, n / N (%)	0/8	1/10 (10.0)	
>=20, n / N (%)	3/67 (4.5)	4/66 (6.1)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-wors15-201-int.sas:t-sf36-gh-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

2.6.3.1 .2 .2 Subgruppenanalysen

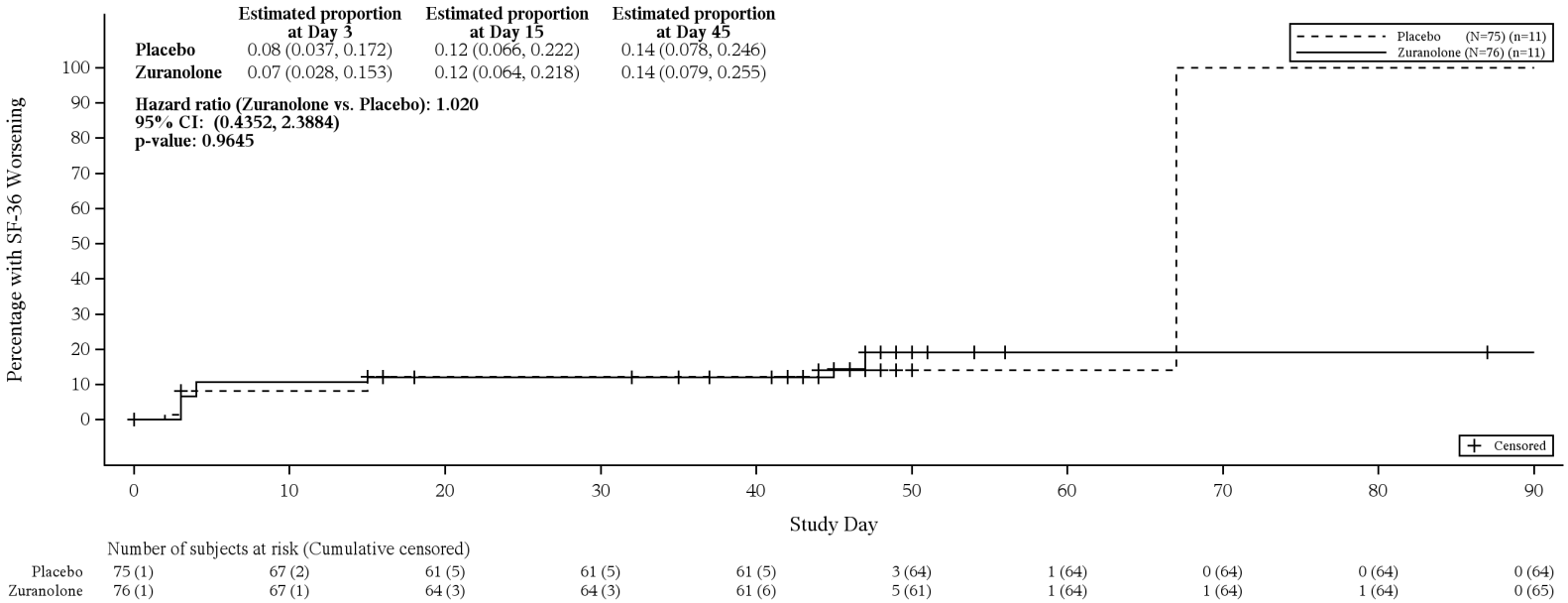
Nicht zutreffend.

2.6.3.2 TTE-Analysen

2.6.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) General Health Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-gh-wors15-tte-201-ovr.sas:f-sf36-gh-wors15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	11 (14.7)	11 (14.5)
Time to first General Health Subscale worsening (days) [3]		
25th percentile - Q1 (95% CI)	67.0 (NE, NE)	NE (45.0, NE)
50th percentile - median (95% CI)	67.0 (NE, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	67.0 (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.020
95% CI for the HR		(0.4352 , 2.3884)
p-value for the HR		0.9645

NOTE 1: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) worsening. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-gh-wors15-tte-201-ovr.sas:t-sf36-gh-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.6.3.2 .2 Subgruppen

2.6.3.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	11 (14.7)	11 (14.5)	
Age Group (years)			
18 - 24, n / N (%)	4/25 (16.0)	4/17 (23.5)	NA
25 - 45, n / N (%)	7/50 (14.0)	7/59 (11.9)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	3/22 (13.6)	5/30 (16.7)	NA
>=28, n / N (%)	8/53 (15.1)	6/46 (13.0)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	3/32 (9.4)	8/31 (25.8)	NA
White, n / N (%)	8/40 (20.0)	3/44 (6.8)	
Antidepressant Use at Baseline			
Yes, n / N (%)	1/13 (7.7)	3/16 (18.8)	0.5000
No, n / N (%)	10/62 (16.1)	8/60 (13.3)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-wors15-tte-201-int.sas:t-sf36-gh-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) General Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	4/21 (19.0)	3/13 (23.1)	NA(a)
25-29.9, n / N (%)	3/20 (15.0)	2/21 (9.5)	NA(b)
>=30, n / N (%)	4/34 (11.8)	6/42 (14.3)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	4/32 (12.5)	5/32 (15.6)	NA
Postpartum, n / N (%)	7/43 (16.3)	6/44 (13.6)	
Family History of PPD			
Yes, n / N (%)	0/10	1/10 (10.0)	0.9891
No/Unknown, n / N (%)	11/65 (16.9)	10/66 (15.2)	
History of PPD			
1st Episode, n / N (%)	10/59 (16.9)	9/66 (13.6)	0.3900
Recurrent Episode, n / N (%)	1/16 (6.3)	2/10 (20.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	2/8 (25.0)	2/10 (20.0)	NA
>=20, n / N (%)	9/67 (13.4)	9/66 (13.6)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-gh-wors15-tte-201-int.sas:t-sf36-gh-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.6.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

2.6.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

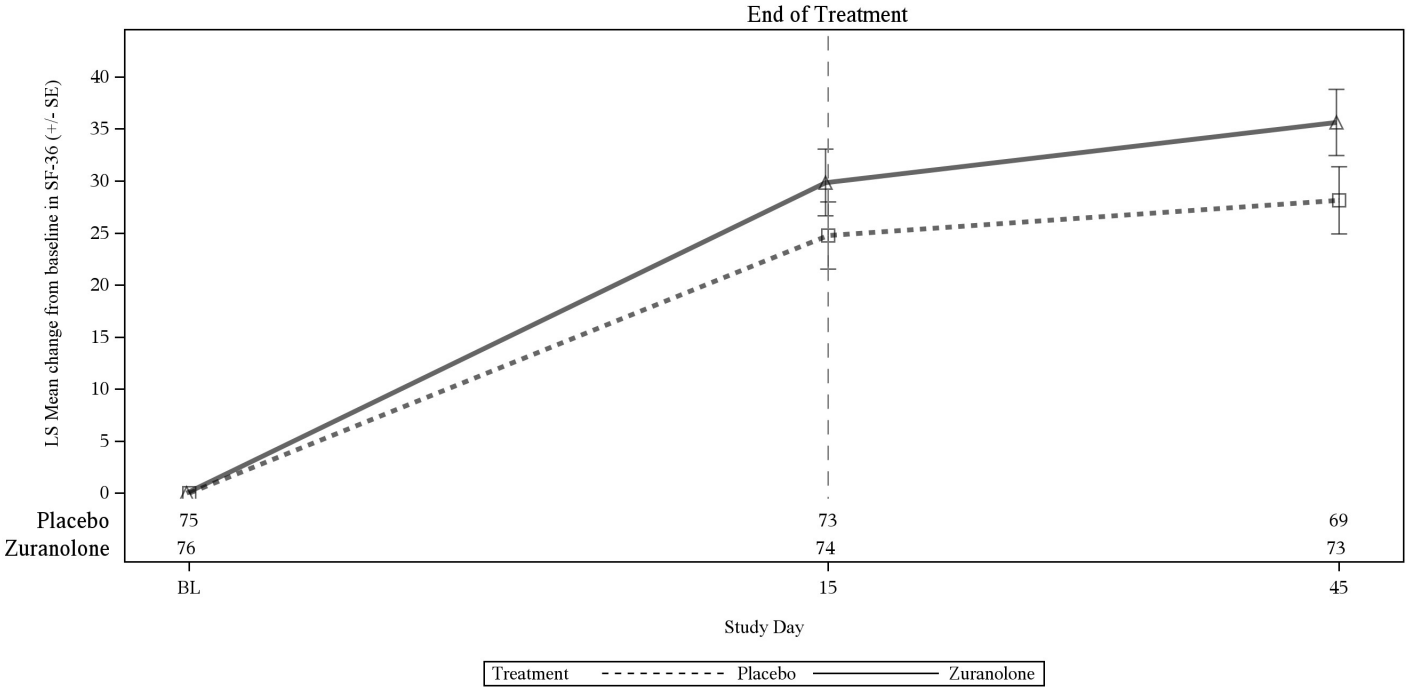
2.7 Vitalität

2.7.1 MMRM

2.7.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-ovr.sas:f-sf36-vs-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	24.76 (3.223)	29.86 (3.193)
95% CI for the LS Mean	18.38, 31.13	23.55, 36.17
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.10 (4.542)
95% CI for the LS Mean		-3.88, 14.08
p-value		0.2633
Hedges' g (Zuranolone vs. Placebo)		0.184
95% CI for Hedges' g		-0.1397, 0.5083
Day 45		
n	69	73
LS Mean (SE)	28.15 (3.247)	35.63 (3.177)
95% CI for the LS Mean	21.74, 34.57	29.34, 41.91
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.47 (4.548)
95% CI for the LS Mean		-1.52, 16.46
p-value		0.1026
Hedges' g (Zuranolone vs. Placebo)		0.274
95% CI for Hedges' g		-0.0562, 0.6050

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-ovr.sas:t-sf36-vs-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.7.1.2 Subgruppen

2.7.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.9033
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.7076
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.8997
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.6299
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-int.sas:t-sf36-vs-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.9587(a)
25-29.9	20	21	0.4157(b)
>=30	34	42	0.4103(c)
Onset of PPD			
3rd Trimester	32	32	0.9490
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.2471
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.5581
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-int.sas:t-sf36-vs-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

2.7.1.2 .2 Subgruppenanalysen

2.7.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Day 15		
n	25	17
LS Mean (SE)	20.82 (5.565)	24.92 (6.762)
95% CI for the LS Mean	9.56, 32.09	11.23, 38.60
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.10 (8.799)
95% CI for the LS Mean		-13.71, 21.90
p-value		0.6442
Hedges' g (Zuranolone vs. Placebo)		0.144
95% CI for Hedges' g		-0.4733, 0.7605
Day 45		
n	25	16
LS Mean (SE)	22.57 (5.905)	29.81 (7.282)
95% CI for the LS Mean	10.61, 34.54	15.08, 44.55
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.24 (9.415)
95% CI for the LS Mean		-11.82, 26.30
p-value		0.4467
Hedges' g (Zuranolone vs. Placebo)		0.241
95% CI for Hedges' g		-0.3883, 0.8711

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Age Group: 217-PPD-201B - ITT population

Page: 2 of 2

Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	26.24 (4.030)	31.81 (3.686)
95% CI for the LS Mean	18.25, 34.24	24.50, 39.13
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.57 (5.464)
95% CI for the LS Mean		-5.26, 16.41
p-value		0.3101
Hedges' g (Zuranolone vs. Placebo)		0.198
95% CI for Hedges' g		-0.1865, 0.5833
Day 45		
n	44	57
LS Mean (SE)	30.54 (3.972)	37.75 (3.540)
95% CI for the LS Mean	22.66, 38.42	30.73, 44.77
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.21 (5.325)
95% CI for the LS Mean		-3.35, 17.77
p-value		0.1787
Hedges' g (Zuranolone vs. Placebo)		0.270
95% CI for Hedges' g		-0.1254, 0.6647

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.7.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	27.60 (6.664)	30.55 (5.834)
95% CI for the LS Mean	14.18, 41.02	18.80, 42.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.95 (8.901)
95% CI for the LS Mean		-14.97, 20.87
p-value		0.7415
Hedges' g (Zuranolone vs. Placebo)		0.093
95% CI for Hedges' g		-0.4656, 0.6518
Day 45		
n	22	28
LS Mean (SE)	28.73 (6.028)	34.33 (5.279)
95% CI for the LS Mean	16.60, 40.87	23.71, 44.96
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.60 (8.063)
95% CI for the LS Mean		-10.63, 21.83
p-value		0.4907
Hedges' g (Zuranolone vs. Placebo)		0.195
95% CI for Hedges' g		-0.3649, 0.7545

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 2 of 2

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	23.48 (3.661)	29.34 (3.857)
95% CI for the LS Mean	16.21, 30.75	21.69, 37.00
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.87 (5.321)
95% CI for the LS Mean		-4.70, 16.43
p-value		0.2730
Hedges' g (Zuranolone vs. Placebo)		0.222
95% CI for Hedges' g		-0.1773, 0.6222
Day 45		
n	47	45
LS Mean (SE)	27.85 (3.940)	36.45 (4.069)
95% CI for the LS Mean	20.02, 35.67	28.37, 44.53
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.61 (5.669)
95% CI for the LS Mean		-2.65, 19.86
p-value		0.1324
Hedges' g (Zuranolone vs. Placebo)		0.314
95% CI for Hedges' g		-0.0973, 0.7252

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.7.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	25.74 (5.272)	32.09 (5.271)
95% CI for the LS Mean	15.19, 36.28	21.54, 42.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.35 (7.536)
95% CI for the LS Mean		-8.72, 21.43
p-value		0.4027
Hedges' g (Zuranolone vs. Placebo)		0.211
95% CI for Hedges' g		-0.2879, 0.7106
Day 45		
n	30	30
LS Mean (SE)	29.60 (5.070)	38.25 (5.070)
95% CI for the LS Mean	19.45, 39.75	28.10, 48.40
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.65 (7.262)
95% CI for the LS Mean		-5.88, 23.19
p-value		0.2383
Hedges' g (Zuranolone vs. Placebo)		0.304
95% CI for Hedges' g		-0.2053, 0.8126

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	23.84 (4.251)	28.17 (4.069)
95% CI for the LS Mean	15.38, 32.30	20.07, 36.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.33 (5.885)
95% CI for the LS Mean		-7.38, 16.05
p-value		0.4638
Hedges' g (Zuranolone vs. Placebo)		0.162
95% CI for Hedges' g		-0.2744, 0.5987
Day 45		
n	36	42
LS Mean (SE)	26.79 (4.411)	34.19 (4.147)
95% CI for the LS Mean	18.01, 35.56	25.93, 42.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.40 (6.056)
95% CI for the LS Mean		-4.65, 19.46
p-value		0.2251
Hedges' g (Zuranolone vs. Placebo)		0.275
95% CI for Hedges' g		-0.1723, 0.7222

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.7.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	23.21 (7.985)	37.55 (7.427)
95% CI for the LS Mean	6.78, 39.65	22.26, 52.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		14.33 (10.924)
95% CI for the LS Mean		-8.15, 36.81
p-value		0.2013
Hedges' g (Zuranolone vs. Placebo)		0.483
95% CI for Hedges' g		-0.2707, 1.2360
Day 45		
n	11	15
LS Mean (SE)	29.06 (7.920)	35.88 (7.001)
95% CI for the LS Mean	12.76, 45.37	21.41, 50.35
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.81 (10.588)
95% CI for the LS Mean		-15.01, 28.64
p-value		0.5258
Hedges' g (Zuranolone vs. Placebo)		0.247
95% CI for Hedges' g		-0.5335, 1.0283

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	25.06 (3.535)	27.95 (3.552)
95% CI for the LS Mean	18.06, 32.06	20.91, 34.98
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.89 (5.015)
95% CI for the LS Mean		-7.04, 12.82
p-value		0.5655
Hedges' g (Zuranolone vs. Placebo)		0.105
95% CI for Hedges' g		-0.2546, 0.4646
Day 45		
n	58	58
LS Mean (SE)	27.93 (3.590)	35.64 (3.590)
95% CI for the LS Mean	20.82, 35.04	28.53, 42.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.71 (5.081)
95% CI for the LS Mean		-2.35, 17.78
p-value		0.1317
Hedges' g (Zuranolone vs. Placebo)		0.280
95% CI for Hedges' g		-0.0857, 0.6458

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.7.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	22.29 (5.908)	30.46 (7.323)
95% CI for the LS Mean	10.20, 34.37	15.49, 45.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.18 (9.452)
95% CI for the LS Mean		-11.15, 27.51
p-value		0.3939
Hedges' g (Zuranolone vs. Placebo)		0.301
95% CI for Hedges' g		-0.4013, 1.0028
Day 45		
n	18	12
LS Mean (SE)	21.21 (6.747)	32.43 (8.327)
95% CI for the LS Mean	7.40, 35.02	15.39, 49.47
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.22 (10.754)
95% CI for the LS Mean		-10.78, 33.23
p-value		0.3054
Hedges' g (Zuranolone vs. Placebo)		0.378
95% CI for Hedges' g		-0.3583, 1.1151

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	26.51 (6.714)	32.22 (6.644)
95% CI for the LS Mean	12.90, 40.13	18.76, 45.69
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.71 (9.632)
95% CI for the LS Mean		-13.81, 25.23
p-value		0.5568
Hedges' g (Zuranolone vs. Placebo)		0.184
95% CI for Hedges' g		-0.4373, 0.8049
Day 45		
n	20	20
LS Mean (SE)	32.14 (6.816)	42.04 (6.745)
95% CI for the LS Mean	18.33, 45.94	28.39, 55.69
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.90 (9.772)
95% CI for the LS Mean		-9.87, 29.68
p-value		0.3172
Hedges' g (Zuranolone vs. Placebo)		0.314
95% CI for Hedges' g		-0.3095, 0.9377

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	26.36 (4.872)	27.58 (4.367)
95% CI for the LS Mean	16.64, 36.07	18.87, 36.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.22 (6.553)
95% CI for the LS Mean		-11.85, 14.29
p-value		0.8528
Hedges' g (Zuranolone vs. Placebo)		0.043
95% CI for Hedges' g		-0.4153, 0.5015
Day 45		
n	31	41
LS Mean (SE)	30.69 (4.463)	32.30 (3.924)
95% CI for the LS Mean	21.79, 39.60	24.47, 40.13
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.61 (5.953)
95% CI for the LS Mean		-10.27, 13.48
p-value		0.7880
Hedges' g (Zuranolone vs. Placebo)		0.064
95% CI for Hedges' g		-0.4031, 0.5302

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.7.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	25.44 (4.861)	28.04 (4.780)
95% CI for the LS Mean	15.72, 35.17	18.47, 37.60
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.59 (6.822)
95% CI for the LS Mean		-11.05, 16.24
p-value		0.7052
Hedges' g (Zuranolone vs. Placebo)		0.095
95% CI for Hedges' g		-0.3996, 0.5888
Day 45		
n	29	30
LS Mean (SE)	31.10 (5.197)	40.86 (5.111)
95% CI for the LS Mean	20.70, 41.51	30.63, 51.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.76 (7.292)
95% CI for the LS Mean		-4.84, 24.35
p-value		0.1861
Hedges' g (Zuranolone vs. Placebo)		0.344
95% CI for Hedges' g		-0.1704, 0.8580

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	24.38 (4.312)	31.00 (4.289)
95% CI for the LS Mean	15.80, 32.96	22.47, 39.53
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.62 (6.098)
95% CI for the LS Mean		-5.51, 18.76
p-value		0.2808
Hedges' g (Zuranolone vs. Placebo)		0.235
95% CI for Hedges' g		-0.1944, 0.6639
Day 45		
n	40	43
LS Mean (SE)	26.23 (4.174)	31.84 (4.081)
95% CI for the LS Mean	17.92, 34.53	23.72, 39.96
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.61 (5.857)
95% CI for the LS Mean		-6.04, 17.26
p-value		0.3410
Hedges' g (Zuranolone vs. Placebo)		0.208
95% CI for Hedges' g		-0.2233, 0.6401

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.7.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	28.25 (8.031)	20.54 (8.036)
95% CI for the LS Mean	11.19, 45.32	3.46, 37.61
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-7.72 (12.140)
95% CI for the LS Mean		-33.34, 17.91
p-value		0.5335
Hedges' g (Zuranolone vs. Placebo)		-0.272
95% CI for Hedges' g		-1.1529, 0.6083
Day 45		
n	9	10
LS Mean (SE)	34.91 (6.595)	20.54 (6.382)
95% CI for the LS Mean	20.88, 48.93	6.89, 34.19
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-14.37 (10.187)
95% CI for the LS Mean		-36.07, 7.33
p-value		0.1786
Hedges' g (Zuranolone vs. Placebo)		-0.619
95% CI for Hedges' g		-1.5410, 0.3026

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	24.57 (3.583)	30.93 (3.541)
95% CI for the LS Mean	17.48, 31.67	23.92, 37.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.36 (5.062)
95% CI for the LS Mean		-3.66, 16.38
p-value		0.2115
Hedges' g (Zuranolone vs. Placebo)		0.222
95% CI for Hedges' g		-0.1273, 0.5705
Day 45		
n	60	63
LS Mean (SE)	27.44 (3.634)	37.62 (3.560)
95% CI for the LS Mean	20.24, 34.63	30.58, 44.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		10.19 (5.110)
95% CI for the LS Mean		0.07, 20.30
p-value		0.0484
Hedges' g (Zuranolone vs. Placebo)		0.357
95% CI for Hedges' g		0.0010, 0.7138

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.7.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	24.42 (3.664)	30.63 (3.504)
95% CI for the LS Mean	17.16, 31.67	23.69, 37.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.21 (5.100)
95% CI for the LS Mean		-3.89, 16.30
p-value		0.2259
Hedges' g (Zuranolone vs. Placebo)		0.218
95% CI for Hedges' g		-0.1365, 0.5731
Day 45		
n	55	64
LS Mean (SE)	28.12 (3.735)	36.49 (3.505)
95% CI for the LS Mean	20.72, 35.51	29.55, 43.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.38 (5.152)
95% CI for the LS Mean		-1.82, 18.58
p-value		0.1065
Hedges' g (Zuranolone vs. Placebo)		0.297
95% CI for Hedges' g		-0.0653, 0.6594

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	25.22 (7.680)	26.31 (9.370)
95% CI for the LS Mean	9.29, 41.16	6.89, 45.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.09 (13.045)
95% CI for the LS Mean		-25.92, 28.10
p-value		0.9341
Hedges' g (Zuranolone vs. Placebo)		0.033
95% CI for Hedges' g		-0.7781, 0.8450
Day 45		
n	14	9
LS Mean (SE)	27.46 (7.232)	31.60 (9.187)
95% CI for the LS Mean	12.36, 42.56	12.51, 50.68
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.14 (12.686)
95% CI for the LS Mean		-22.23, 30.51
p-value		0.7474
Hedges' g (Zuranolone vs. Placebo)		0.134
95% CI for Hedges' g		-0.7039, 0.9727

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

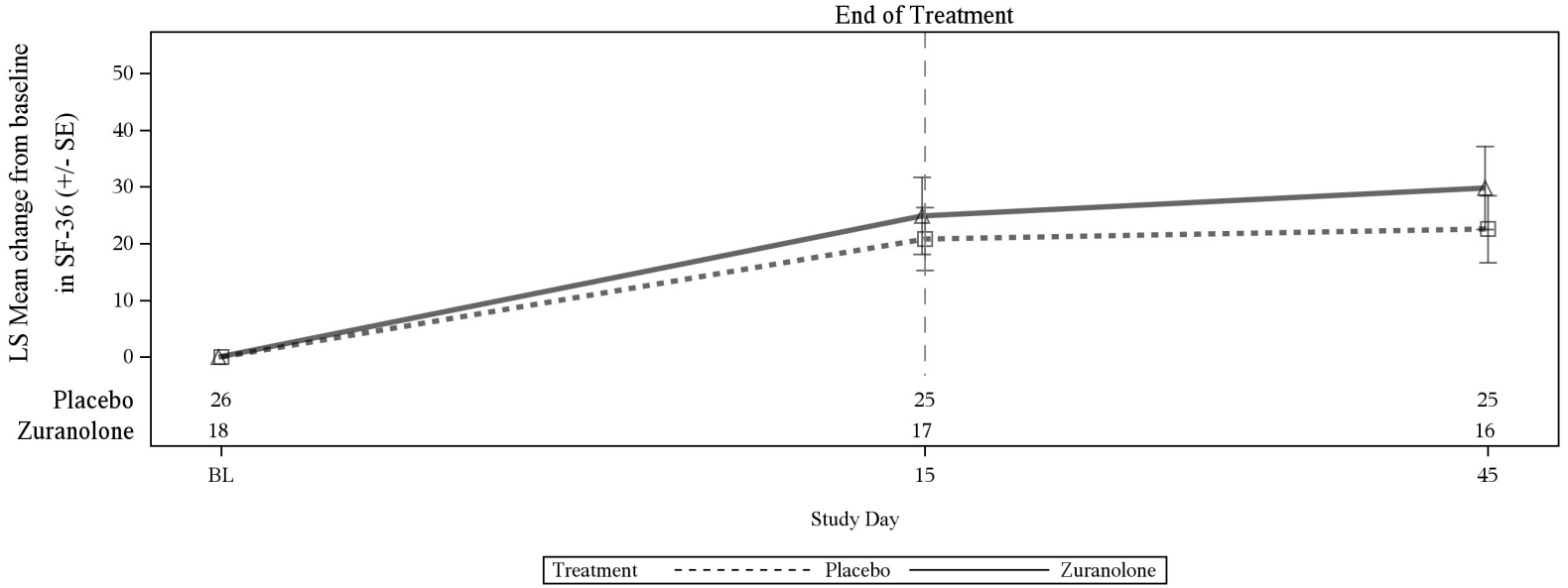
Source: biib125/v_a/germany_amnog/t-sf36-vs-mmrm-201-by.sas:t-sf36-vs-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.7.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

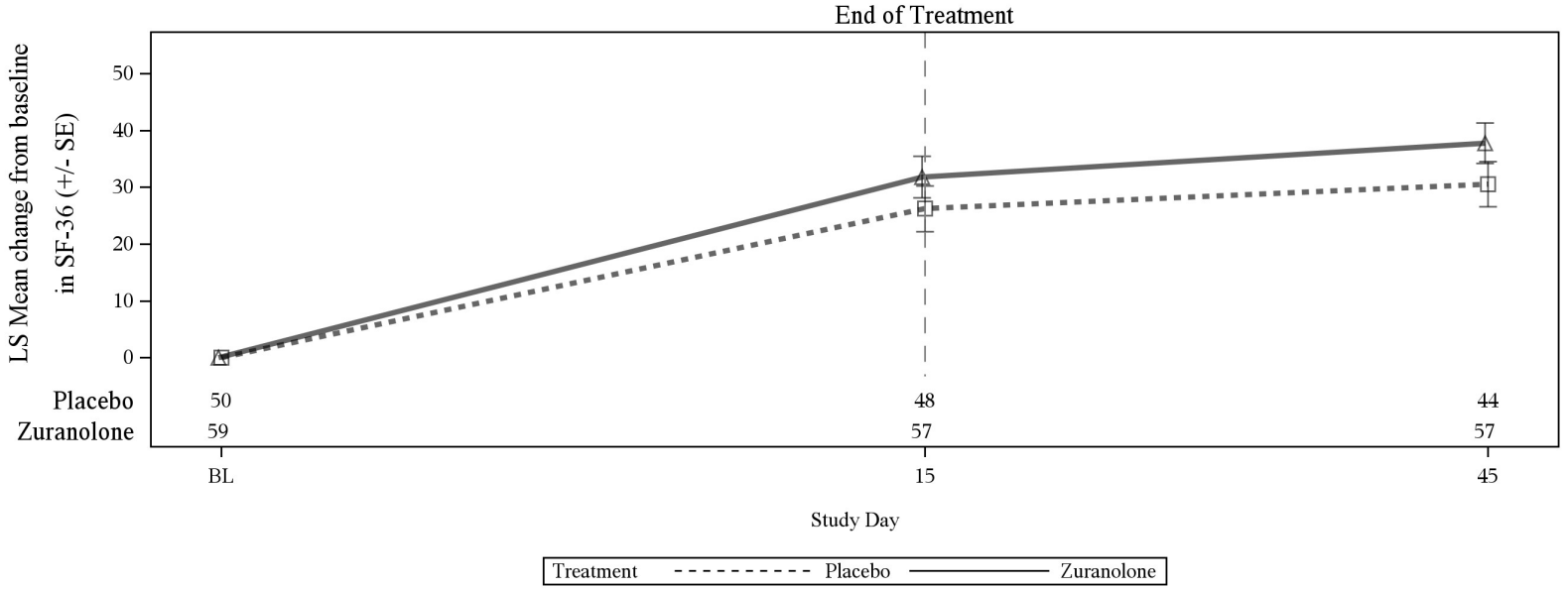
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

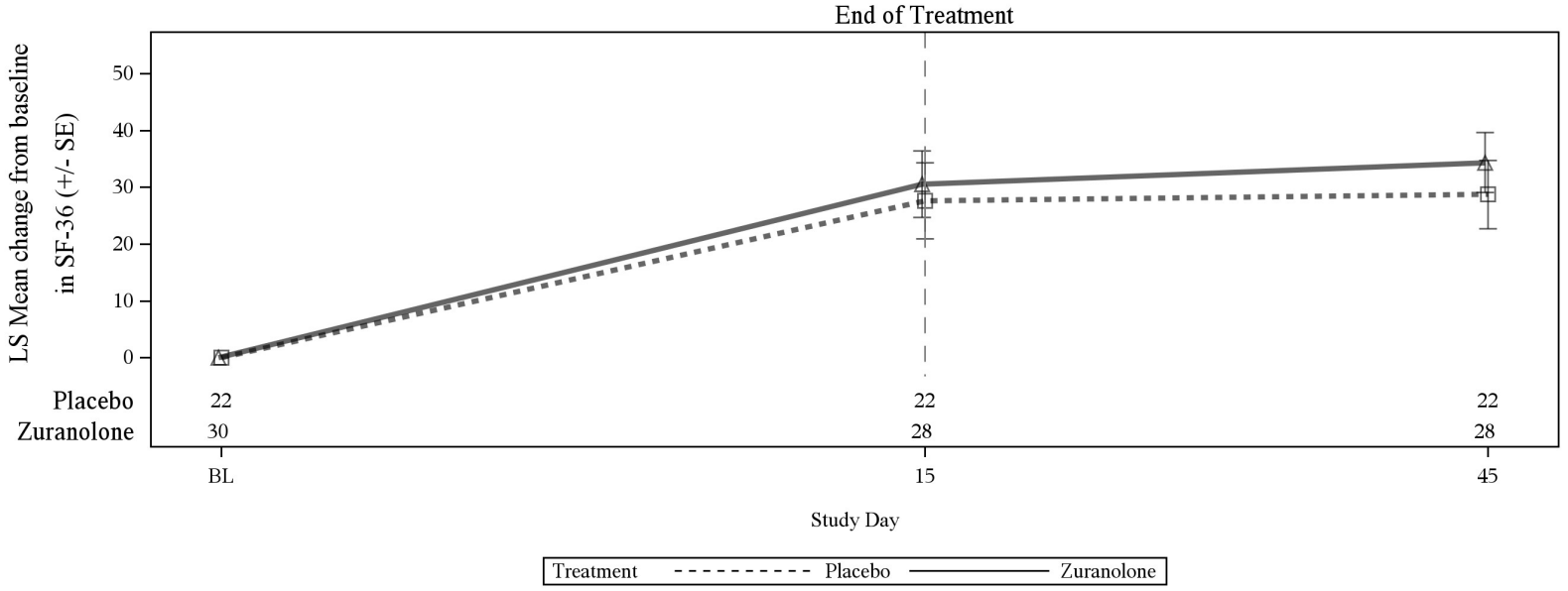
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

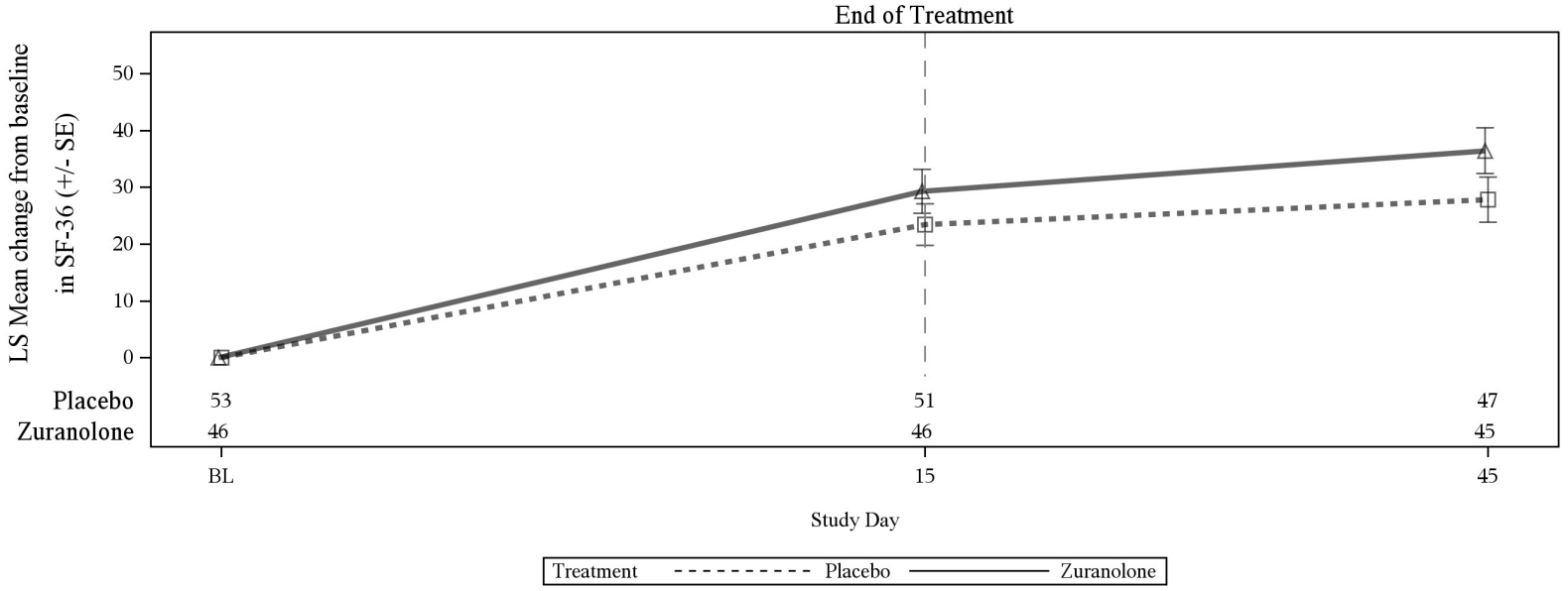
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

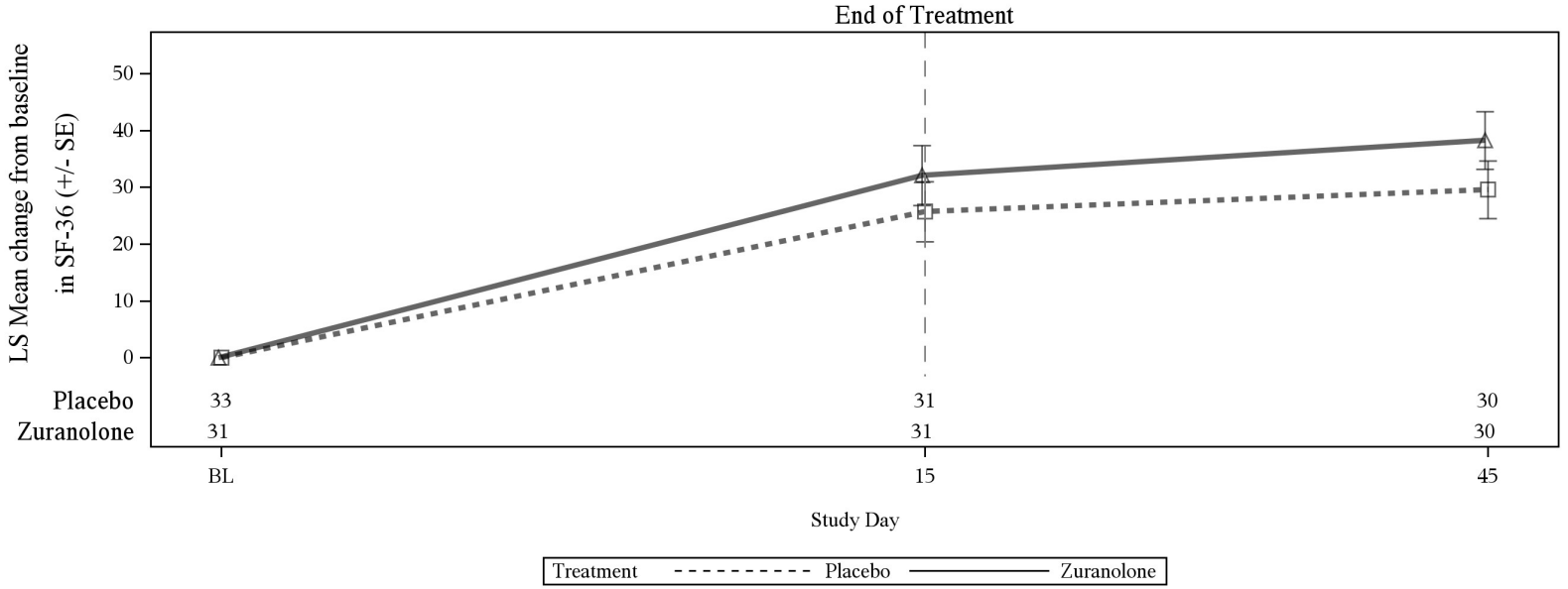
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

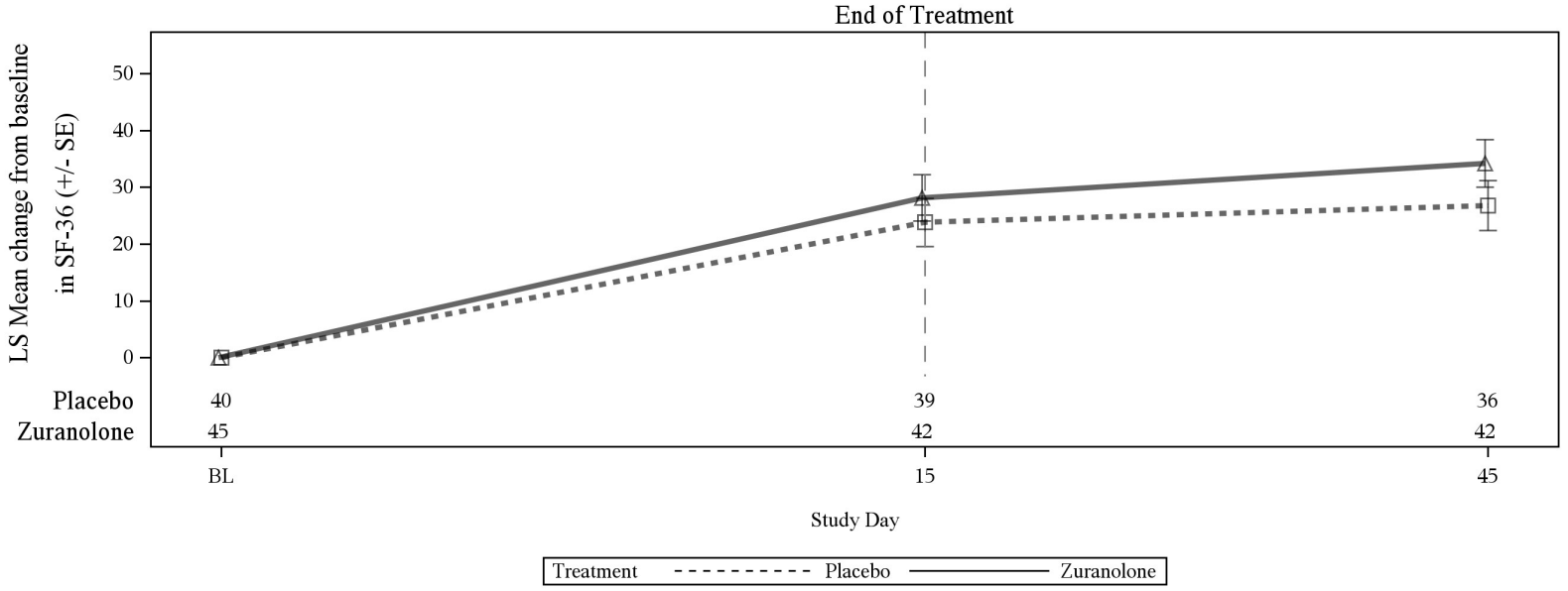
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

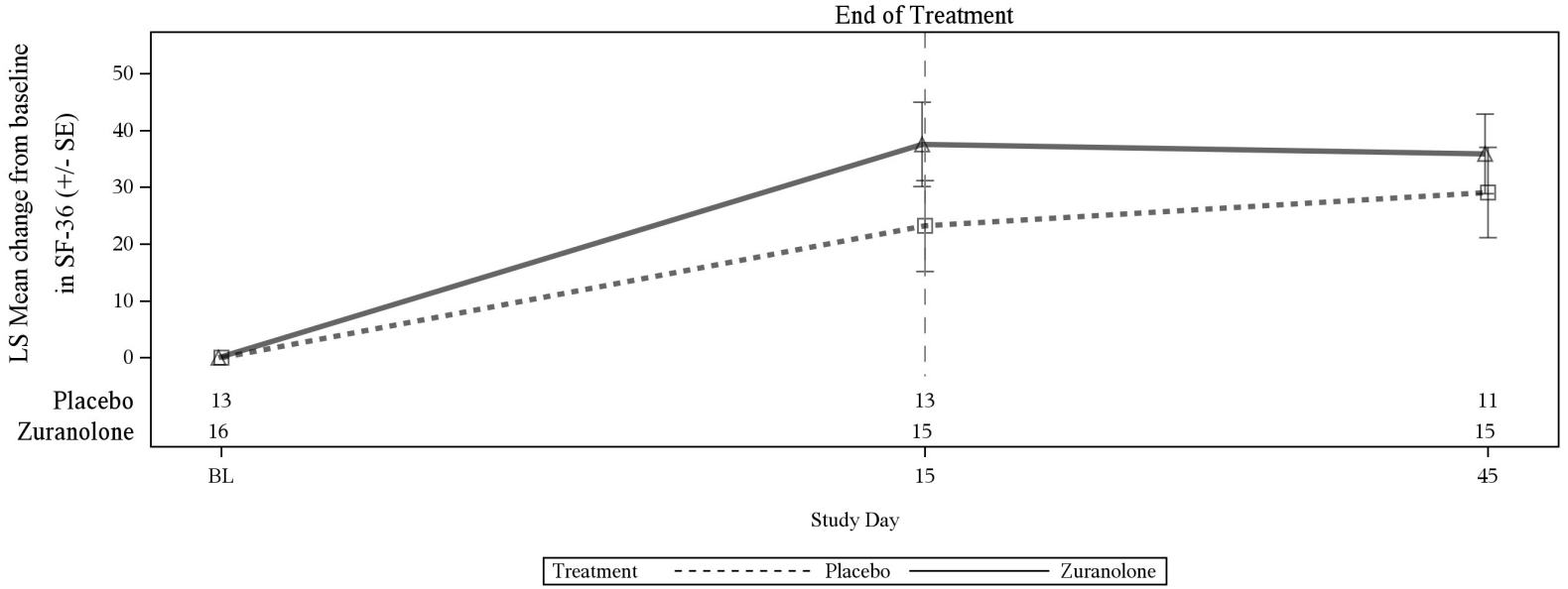
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 7 of 17

Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

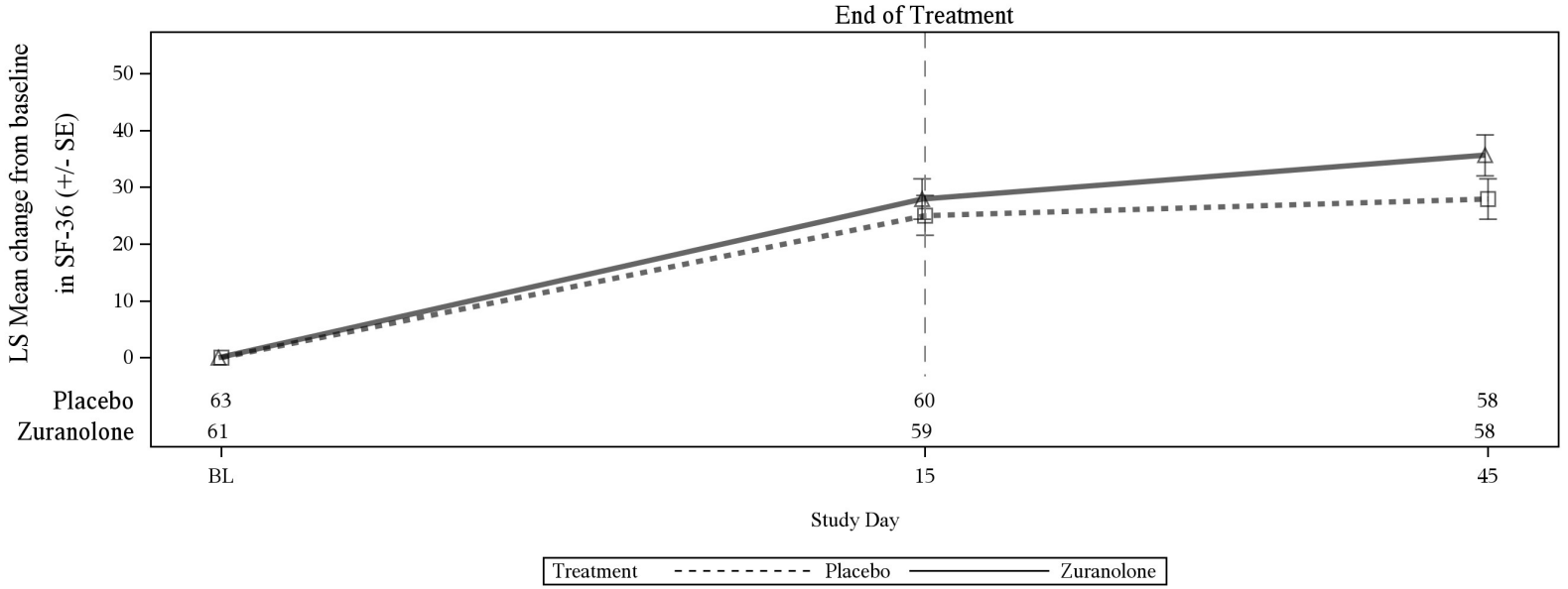
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

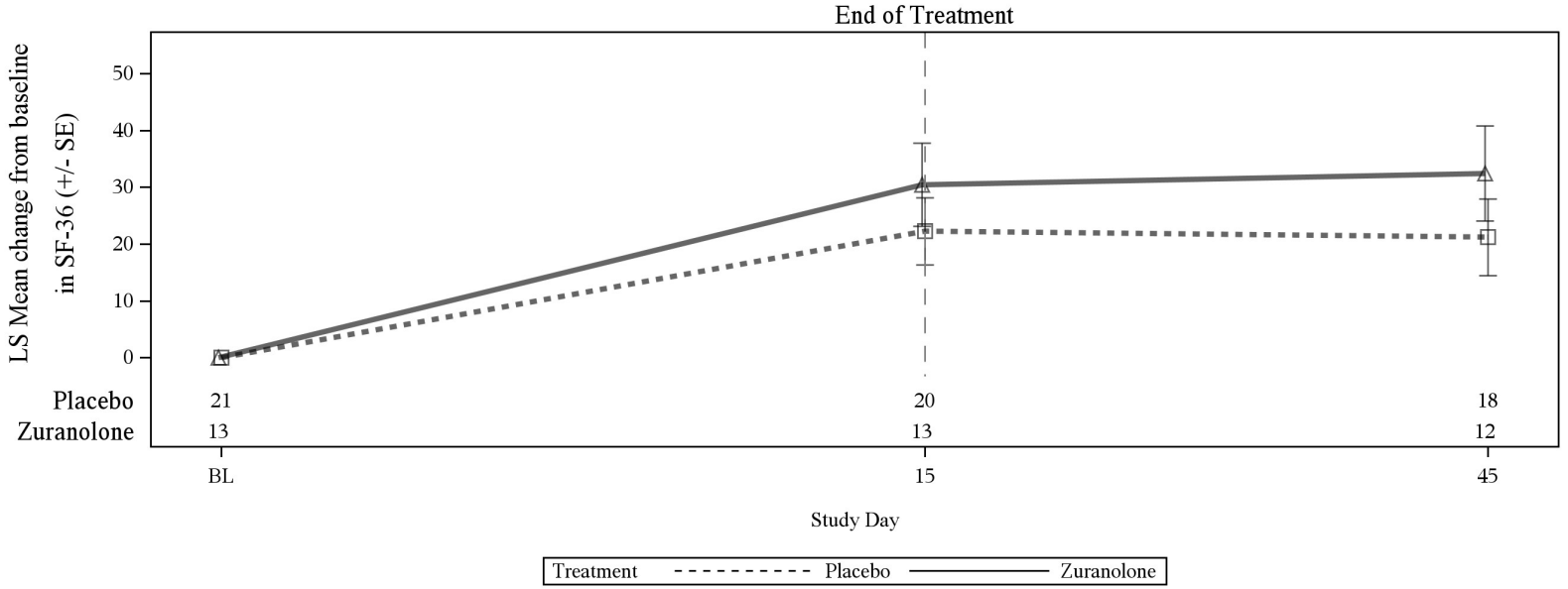
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 9 of 17

BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

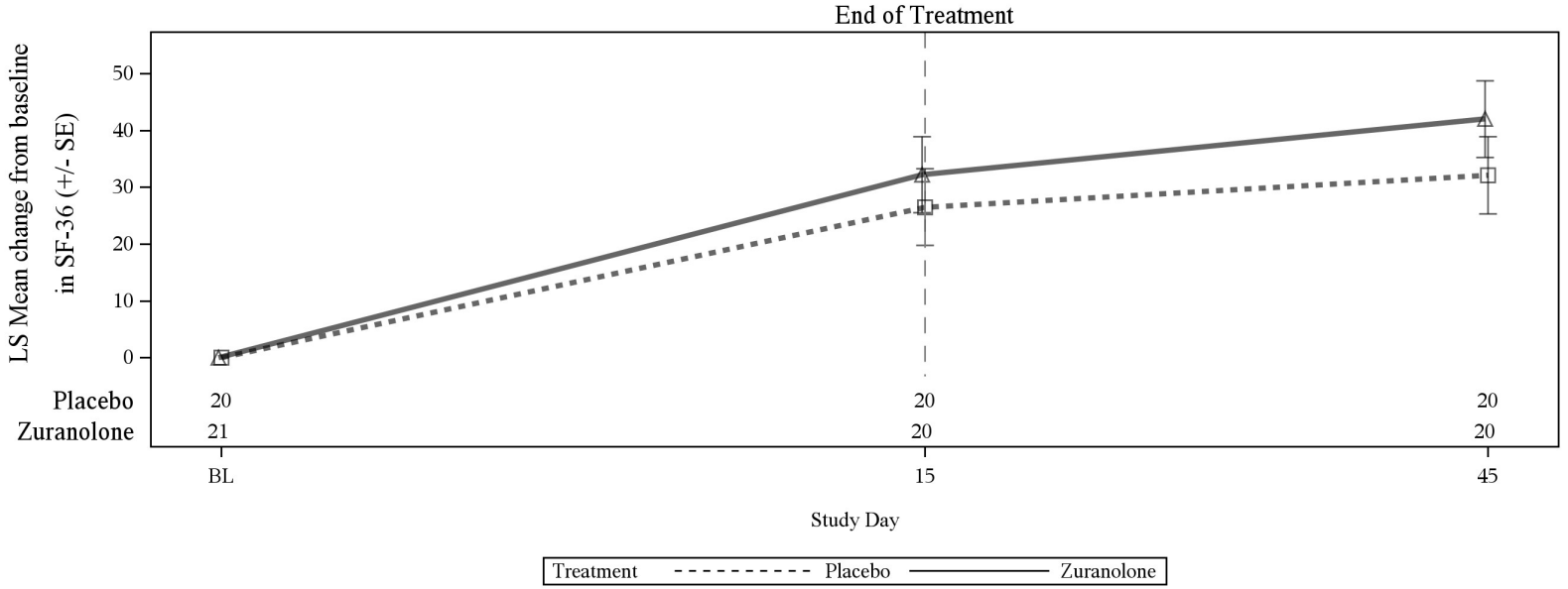
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 10 of 17

BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

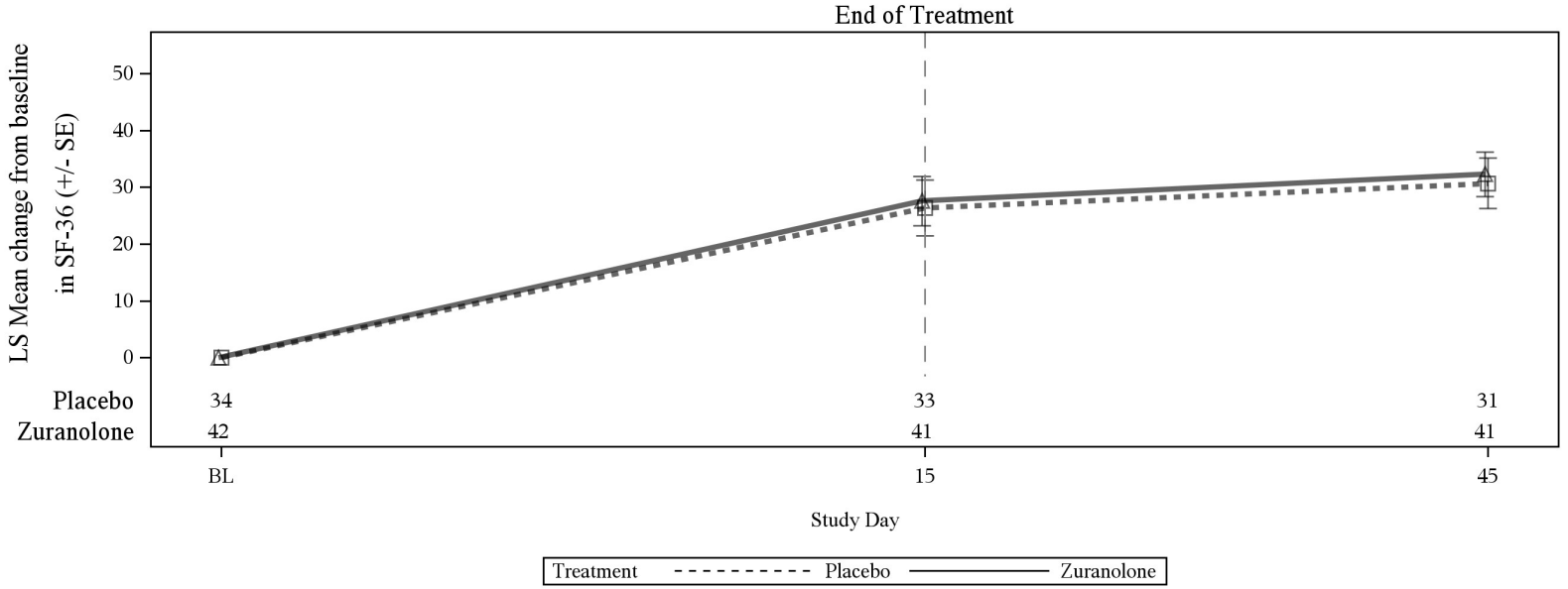
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 11 of 17

BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

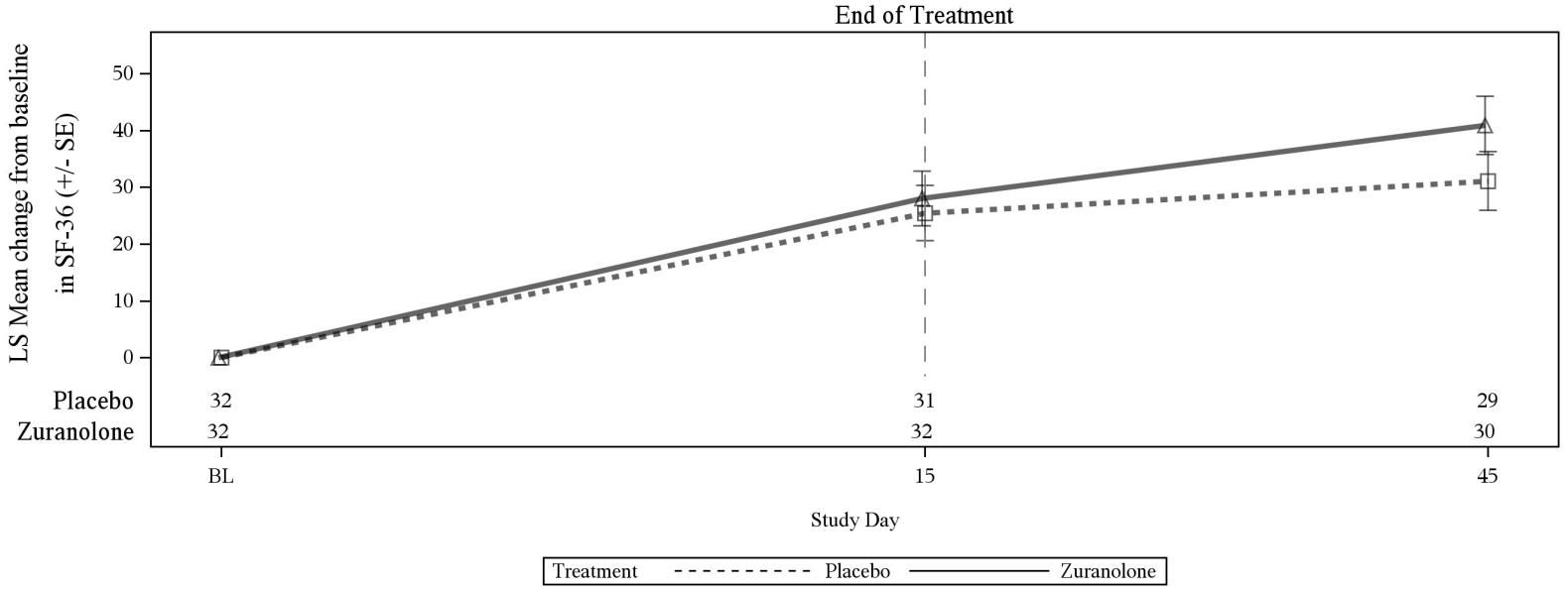
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 12 of 17

Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

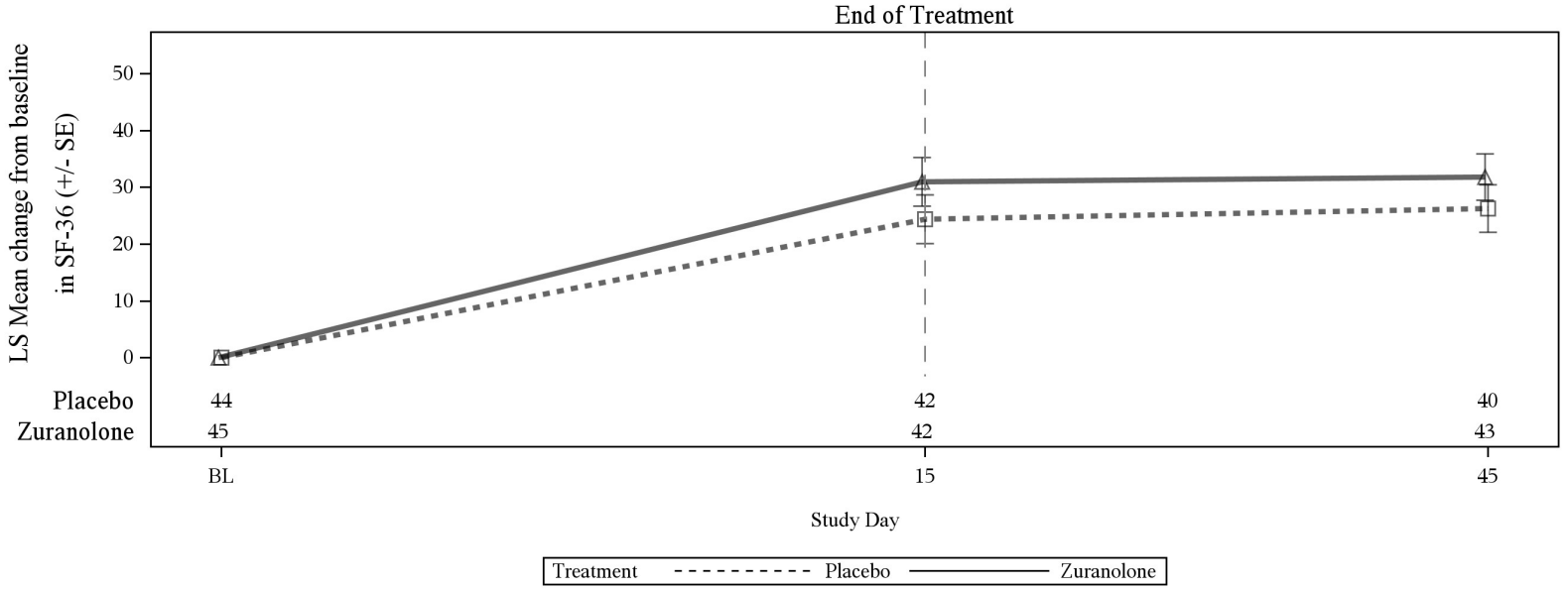
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 13 of 17

Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

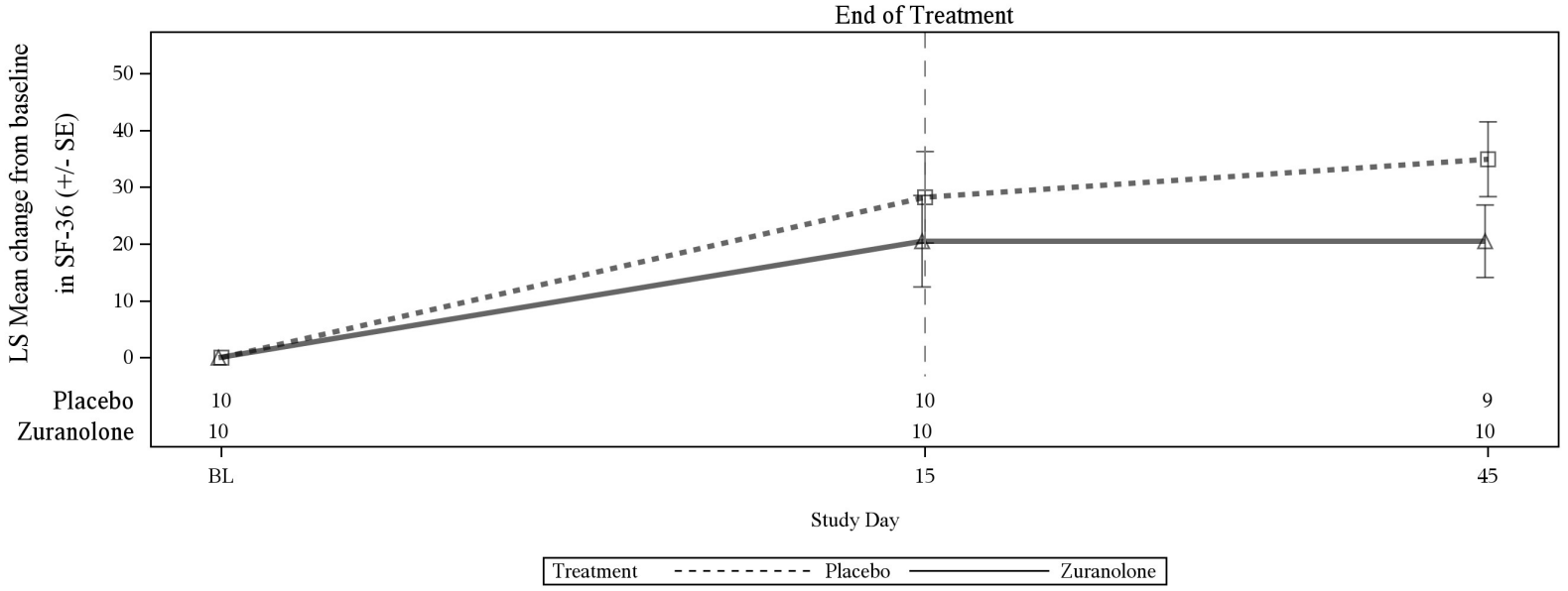
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

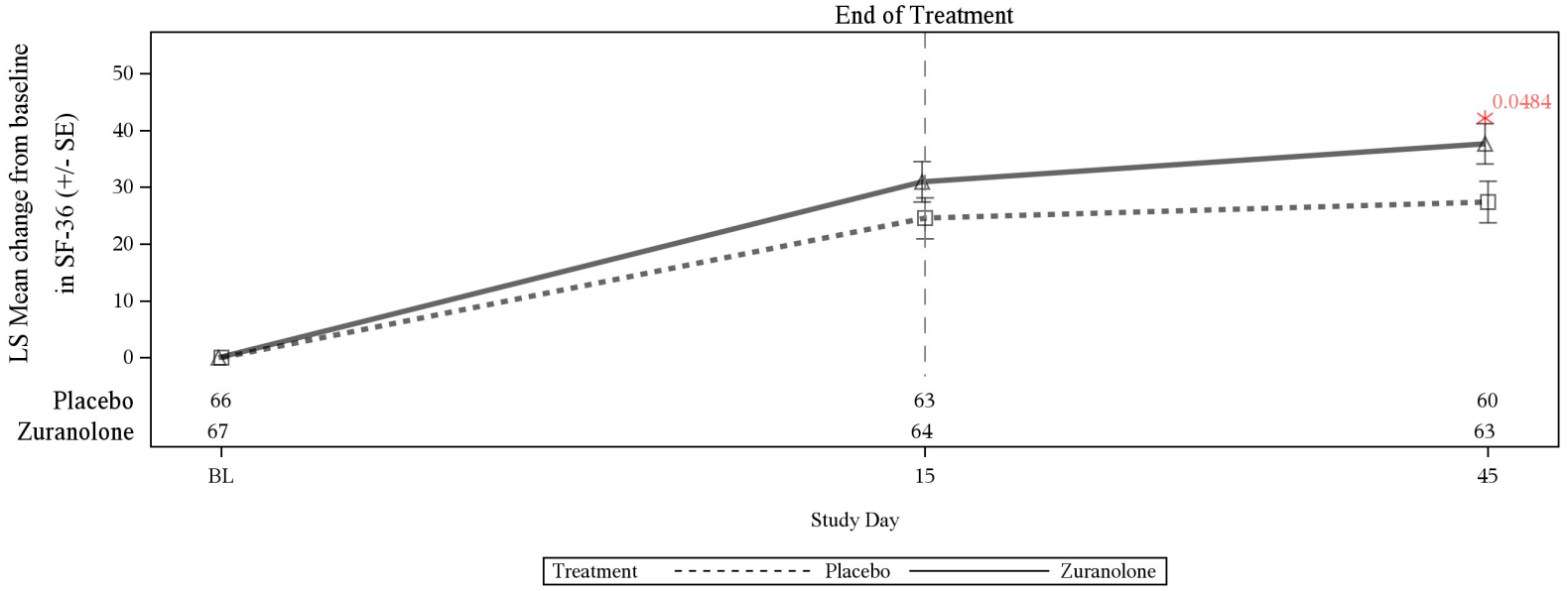
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 15 of 17

Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

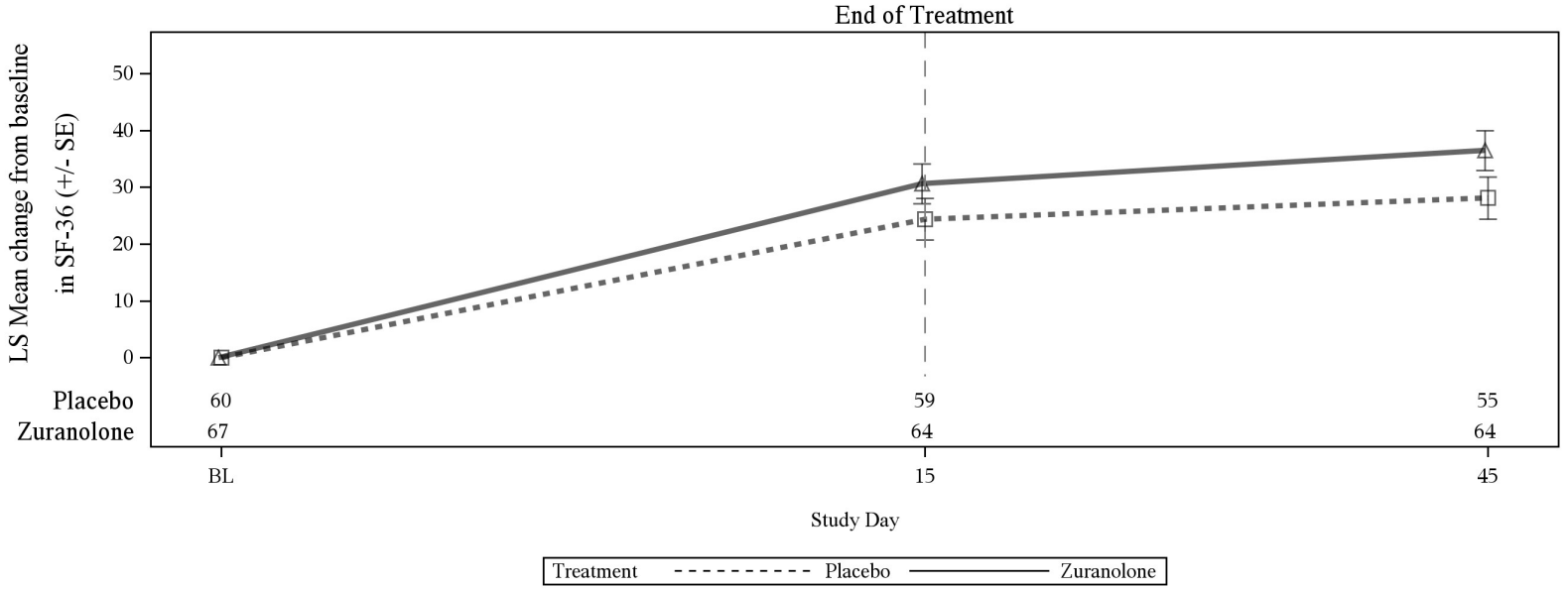
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 16 of 17

History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

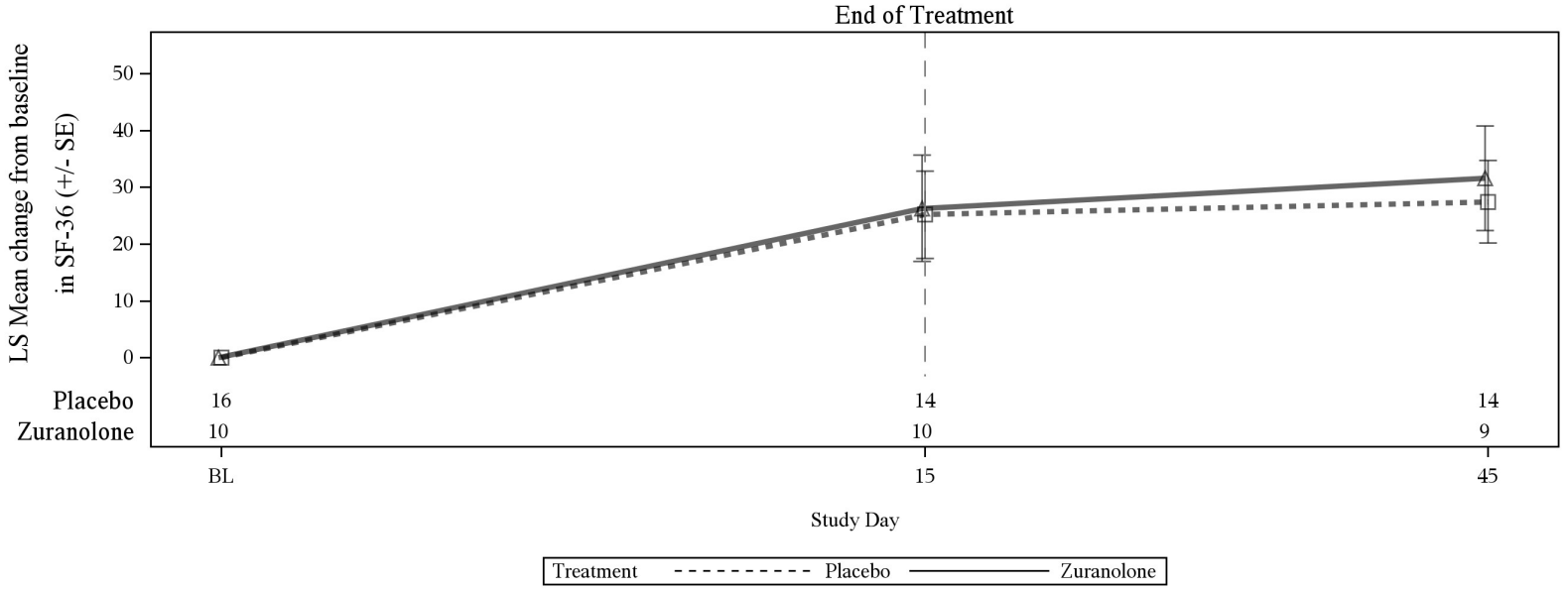
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Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Vitality Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 17 of 17

History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-vs-mmrm-201-by.sas:f-sf36-vs-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

2.7.2 Ansprechen

2.7.2.1 Responder-Analysen

2.7.2.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with a response, n (%) [2]	40 (53.3)	45 (59.2)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.104
95% CI for the RR		(0.840, 1.451)
p-value for RR		0.4779
OR - Odds Ratio (Zuranolone vs. Placebo)		1.218
95% CI for the OR		(0.638, 2.326)
p-value for OR		0.5498
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.051
95% CI for the ARR		(-0.105, 0.206)
p-value for ARR		0.5226

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-ovr.sas:t-sf36-vs-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	42 (56.0)	54 (71.1)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.257
95% CI for the RR		(0.983, 1.609)
p-value for RR		0.0688
OR - Odds Ratio (Zuranolone vs. Placebo)		1.868
95% CI for the OR		(0.937, 3.723)
p-value for OR		0.0758
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.140
95% CI for the ARR		(-0.012, 0.292)
p-value for ARR		0.0707

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-ovr.sas:t-sf36-vs-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.7.2.1 .2 Subgruppen

2.7.2.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	40 (53.3)	45 (59.2)	
Number of subjects with response at Day 45, n (%)	42 (56.0)	54 (71.1)	
Age Group (years)			0.6700
Day 15			
18 - 24, n / N (%)	13/25 (52.0)	9/17 (52.9)	
25 - 45, n / N (%)	27/50 (54.0)	36/59 (61.0)	
Day 45			
18 - 24, n / N (%)	14/25 (56.0)	11/17 (64.7)	
25 - 45, n / N (%)	28/50 (56.0)	43/59 (72.9)	

NOTE 1: p-value is derived using Method 1, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-int.sas:t-sf36-vs-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.4355
Day 15			
<28, n / N (%)	12/22 (54.5)	16/30 (53.3)	
>=28, n / N (%)	28/53 (52.8)	29/46 (63.0)	
Day 45			
<28, n / N (%)	14/22 (63.6)	22/30 (73.3)	
>=28, n / N (%)	28/53 (52.8)	32/46 (69.6)	
Race Group (Black or African American, White)			0.6615
Day 15			
Black or African American, n / N (%)	17/32 (53.1)	21/31 (67.7)	
White, n / N (%)	21/40 (52.5)	23/44 (52.3)	
Day 45			
Black or African American, n / N (%)	18/32 (56.3)	24/31 (77.4)	
White, n / N (%)	22/40 (55.0)	29/44 (65.9)	

NOTE 1: p-value is derived using Method 1, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-int.sas:t-sf36-vs-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.6079
Day 15			
Yes, n / N (%)	7/13 (53.8)	11/16 (68.8)	
No, n / N (%)	33/62 (53.2)	34/60 (56.7)	
Day 45			
Yes, n / N (%)	7/13 (53.8)	12/16 (75.0)	
No, n / N (%)	35/62 (56.5)	42/60 (70.0)	

NOTE 1: p-value is derived using Method 1, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-int.sas:t-sf36-vs-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.6134(a) 0.5643(b) 0.9949(c)
Day 15			
<=24.9, n / N (%)	11/21 (52.4)	9/13 (69.2)	
25-29.9, n / N (%)	11/20 (55.0)	14/21 (66.7)	
>=30, n / N (%)	18/34 (52.9)	22/42 (52.4)	
Day 45			
<=24.9, n / N (%)	10/21 (47.6)	9/13 (69.2)	
25-29.9, n / N (%)	13/20 (65.0)	15/21 (71.4)	
>=30, n / N (%)	19/34 (55.9)	30/42 (71.4)	

NOTE 1: p-value is derived using Method 1, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.4604
Day 15			
3rd Trimester, n / N (%)	16/32 (50.0)	20/32 (62.5)	
Postpartum, n / N (%)	24/43 (55.8)	25/44 (56.8)	
Day 45			
3rd Trimester, n / N (%)	19/32 (59.4)	25/32 (78.1)	
Postpartum, n / N (%)	23/43 (53.5)	29/44 (65.9)	
Family History of PPD			0.1469
Day 15			
Yes, n / N (%)	7/10 (70.0)	4/10 (40.0)	
No/Unknown, n / N (%)	33/65 (50.8)	41/66 (62.1)	
Day 45			
Yes, n / N (%)	7/10 (70.0)	6/10 (60.0)	
No/Unknown, n / N (%)	35/65 (53.8)	48/66 (72.7)	

NOTE 1: p-value is derived using Method 1, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-int.sas:t-sf36-vs-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.5204
Day 15			
1st Episode, n / N (%)	32/59 (54.2)	39/66 (59.1)	
Recurrent Episode, n / N (%)	8/16 (50.0)	6/10 (60.0)	
Day 45			
1st Episode, n / N (%)	34/59 (57.6)	47/66 (71.2)	
Recurrent Episode, n / N (%)	8/16 (50.0)	7/10 (70.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	5/8 (62.5)	4/10 (40.0)	
>=20, n / N (%)	35/67 (52.2)	41/66 (62.1)	
Day 45			
<20, n / N (%)	6/8 (75.0)	5/10 (50.0)	
>=20, n / N (%)	36/67 (53.7)	49/66 (74.2)	

NOTE 1: p-value is derived using Method 1, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-int.sas:t-sf36-vs-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

2.7.2.1 .2 .2 Subgruppenanalysen

2.7.2.1 .2 .2 .1 Alter

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 15		
Number of subjects with a response, n (%) [2]	13 (52.0)	9 (52.9)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.001
95% CI for the RR		(0.559, 1.792)
p-value for RR		0.9974
Day 45		
Number of subjects with a response, n (%) [2]	14 (56.0)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.147
95% CI for the RR		(0.695, 1.891)
p-value for RR		0.5915

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 15		
Number of subjects with a response, n (%) [2]	27 (54.0)	36 (61.0)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.132
95% CI for the RR		(0.833, 1.539)
p-value for RR		0.4271
Day 45		
Number of subjects with a response, n (%) [2]	28 (56.0)	43 (72.9)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.281
95% CI for the RR		(0.965, 1.702)
p-value for RR		0.0866

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.7.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 15		
Number of subjects with a response, n (%) [2]	12 (54.5)	16 (53.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.996
95% CI for the RR		(0.595, 1.666)
p-value for RR		0.9865
Day 45		
Number of subjects with a response, n (%) [2]	14 (63.6)	22 (73.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.166
95% CI for the RR		(0.792, 1.716)
p-value for RR		0.4369

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 15		
Number of subjects with a response, n (%) [2]	28 (52.8)	29 (63.0)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.227
95% CI for the RR		(0.897, 1.679)
p-value for RR		0.2003
Day 45		
Number of subjects with a response, n (%) [2]	28 (52.8)	32 (69.6)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.323
95% CI for the RR		(0.980, 1.786)
p-value for RR		0.0677

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.7.2.1 .2 .2 .3 Abstammung

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 15		
Number of subjects with a response, n (%) [2]	17 (53.1)	21 (67.7)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.151
95% CI for the RR		(0.773, 1.713)
p-value for RR		0.4891
Day 45		
Number of subjects with a response, n (%) [2]	18 (56.3)	24 (77.4)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.282
95% CI for the RR		(0.891, 1.844)
p-value for RR		0.1805

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 15		
Number of subjects with a response, n (%) [2]	21 (52.5)	23 (52.3)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.018
95% CI for the RR		(0.691, 1.500)
p-value for RR		0.9278
Day 45		
Number of subjects with a response, n (%) [2]	22 (55.0)	29 (65.9)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.197
95% CI for the RR		(0.844, 1.696)
p-value for RR		0.3136

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.7.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 15		
Number of subjects with a response, n (%) [2]	7 (53.8)	11 (68.8)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.231
95% CI for the RR		(0.754, 2.011)
p-value for RR		0.4060
Day 45		
Number of subjects with a response, n (%) [2]	7 (53.8)	12 (75.0)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.399
95% CI for the RR		(0.800, 2.444)
p-value for RR		0.2386

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 15		
Number of subjects with a response, n (%) [2]	33 (53.2)	34 (56.7)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.062
95% CI for the RR		(0.774, 1.458)
p-value for RR		0.7083
Day 45		
Number of subjects with a response, n (%) [2]	35 (56.5)	42 (70.0)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.226
95% CI for the RR		(0.933, 1.611)
p-value for RR		0.1441

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.7.2.1 .2 .2 .5 BMI

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 15		
Number of subjects with a response, n (%) [2]	11 (52.4)	9 (69.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.250
95% CI for the RR		(0.742, 2.107)
p-value for RR		0.4015
Day 45		
Number of subjects with a response, n (%) [2]	10 (47.6)	9 (69.2)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.375
95% CI for the RR		(0.772, 2.451)
p-value for RR		0.2794

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 15		
Number of subjects with a response, n (%) [2]	11 (55.0)	14 (66.7)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.050
95% CI for the RR		(0.603, 1.828)
p-value for RR		0.8634
Day 45		
Number of subjects with a response, n (%) [2]	13 (65.0)	15 (71.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.952
95% CI for the RR		(0.590, 1.536)
p-value for RR		0.8397

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 15		
Number of subjects with a response, n (%) [2]	18 (52.9)	22 (52.4)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.990
95% CI for the RR		(0.643, 1.523)
p-value for RR		0.9618
Day 45		
Number of subjects with a response, n (%) [2]	19 (55.9)	30 (71.4)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.278
95% CI for the RR		(0.893, 1.830)
p-value for RR		0.1796

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.7.2.1 .2 .2 .6 Beginn der PPD

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 15		
Number of subjects with a response, n (%) [2]	16 (50.0)	20 (62.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.219
95% CI for the RR		(0.796, 1.867)
p-value for RR		0.3617
Day 45		
Number of subjects with a response, n (%) [2]	19 (59.4)	25 (78.1)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.278
95% CI for the RR		(0.915, 1.786)
p-value for RR		0.1495

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 15		
Number of subjects with a response, n (%) [2]	24 (55.8)	25 (56.8)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.956
95% CI for the RR		(0.691, 1.323)
p-value for RR		0.7860
Day 45		
Number of subjects with a response, n (%) [2]	23 (53.5)	29 (65.9)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.176
95% CI for the RR		(0.840, 1.646)
p-value for RR		0.3461

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.7.2.1 .2 .2 .7 PPD in der Familie

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 15		
Number of subjects with a response, n (%) [2]	7 (70.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.578
95% CI for the RR		(0.224, 1.490)
p-value for RR		0.2562
Day 45		
Number of subjects with a response, n (%) [2]	7 (70.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.866
95% CI for the RR		(0.405, 1.851)
p-value for RR		0.7109

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 15		
Number of subjects with a response, n (%) [2]	33 (50.8)	41 (62.1)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.190
95% CI for the RR		(0.877, 1.614)
p-value for RR		0.2647
Day 45		
Number of subjects with a response, n (%) [2]	35 (53.8)	48 (72.7)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.313
95% CI for the RR		(1.001, 1.722)
p-value for RR		0.0490

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.7.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 15		
Number of subjects with a response, n (%) [2]	32 (54.2)	39 (59.1)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.055
95% CI for the RR		(0.776, 1.433)
p-value for RR		0.7330
Day 45		
Number of subjects with a response, n (%) [2]	34 (57.6)	47 (71.2)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.196
95% CI for the RR		(0.913, 1.567)
p-value for RR		0.1933

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 15		
Number of subjects with a response, n (%) [2]	8 (50.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.354
95% CI for the RR		(0.754, 2.431)
p-value for RR		0.3107
Day 45		
Number of subjects with a response, n (%) [2]	8 (50.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.579
95% CI for the RR		(0.904, 2.759)
p-value for RR		0.1083

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Vitality subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Vitality subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

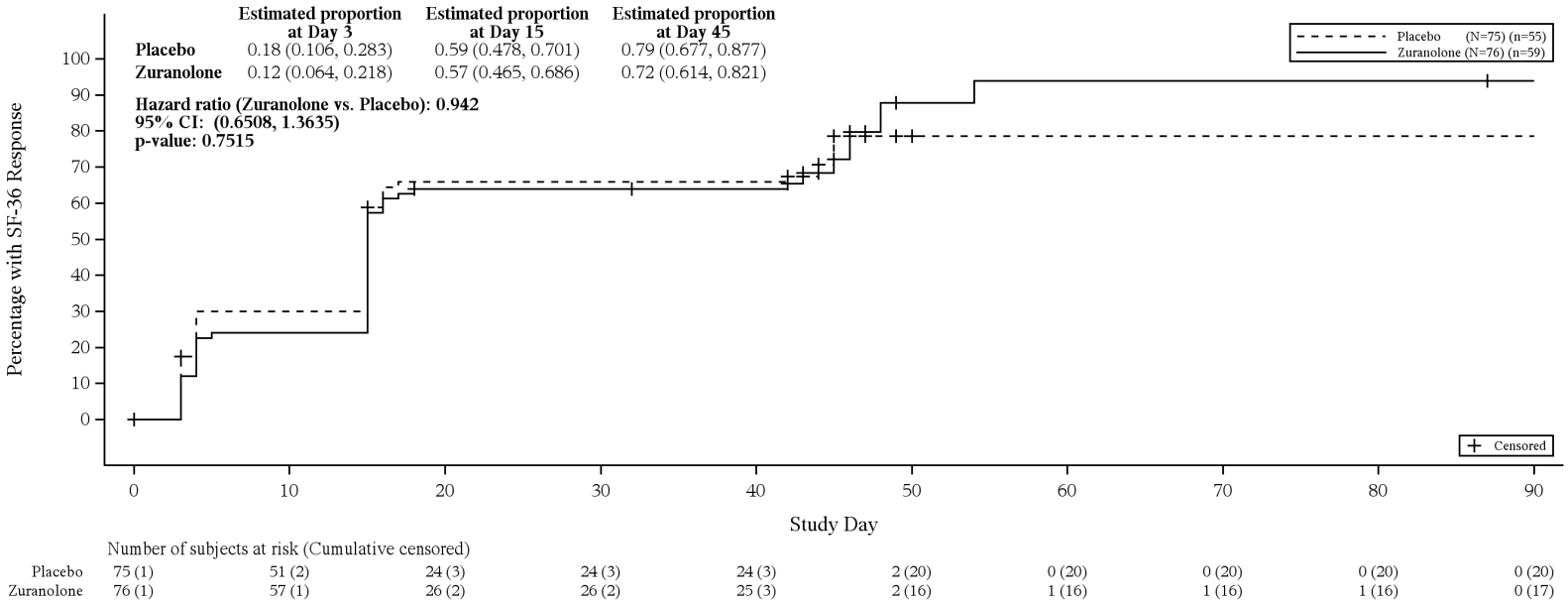
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-201-by.sas:t-sf36-vs-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.7.2.2 TTE-Analysen

2.7.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-ovr.sas:f-sf36-vs-resp15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	55 (73.3)	59 (77.6)
Time to first SF-36 Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 16.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	45.0 (16.0, NE)	46.0 (42.0 , 54.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.942
95% CI for the HR		(0.6508 , 1.3635)
p-value for the HR		0.7515

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-ovr.sas:t-sf36-vs-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.7.2.2 .2 Subgruppen

2.7.2.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	55 (73.3)	59 (77.6)	
Age Group (years)			
18 - 24, n / N (%)	17/25 (68.0)	14/17 (82.4)	0.6451
25 - 45, n / N (%)	38/50 (76.0)	45/59 (76.3)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	15/22 (68.2)	22/30 (73.3)	0.5928
>=28, n / N (%)	40/53 (75.5)	37/46 (80.4)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	25/32 (78.1)	26/31 (83.9)	0.8138
White, n / N (%)	28/40 (70.0)	32/44 (72.7)	
Antidepressant Use at Baseline			
Yes, n / N (%)	8/13 (61.5)	13/16 (81.3)	0.1095
No, n / N (%)	47/62 (75.8)	46/60 (76.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-int.sas:t-sf36-vs-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	14/21 (66.7)	11/13 (84.6)	0.6407(a)
25-29.9, n / N (%)	16/20 (80.0)	16/21 (76.2)	0.3977(b)
>=30, n / N (%)	25/34 (73.5)	32/42 (76.2)	0.7153(c)
Onset of PPD			
3rd Trimester, n / N (%)	24/32 (75.0)	28/32 (87.5)	0.5118
Postpartum, n / N (%)	31/43 (72.1)	31/44 (70.5)	
Family History of PPD			
Yes, n / N (%)	9/10 (90.0)	6/10 (60.0)	0.1401
No/Unknown, n / N (%)	46/65 (70.8)	53/66 (80.3)	
History of PPD			
1st Episode, n / N (%)	44/59 (74.6)	52/66 (78.8)	0.8194
Recurrent Episode, n / N (%)	11/16 (68.8)	7/10 (70.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	6/8 (75.0)	6/10 (60.0)	NA
>=20, n / N (%)	49/67 (73.1)	53/66 (80.3)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-int.sas:t-sf36-vs-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.7.2.2 .2 .2 Subgruppenanalysen

2.7.2.2 .2 .2 .1 Alter

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	17 (68.0)	14 (82.4)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 45.0)	15.0 (3.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (16.0, NE)	45.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.150
95% CI for the HR		(0.5487 , 2.4108)
p-value for the HR		0.7111

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	38 (76.0)	45 (76.3)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 16.0)	15.0 (15.0 , 18.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	46.0 (18.0 , 48.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.894
95% CI for the HR		(0.5782 , 1.3821)
p-value for the HR		0.6139

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.7.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	15 (68.2)	22 (73.3)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 45.0)	15.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	46.0 (42.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.159
95% CI for the HR		(0.5983 , 2.2441)
p-value for the HR		0.6621

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	40 (75.5)	37 (80.4)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 16.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	44.0 (16.0, NE)	46.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.908
95% CI for the HR		(0.5776 , 1.4281)
p-value for the HR		0.6767

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.7.2.2 .2 .2 .3 Abstammung

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	25 (78.1)	26 (83.9)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	5.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 16.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	44.0 (15.0, NE)	45.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.827
95% CI for the HR		(0.4703 , 1.4530)
p-value for the HR		0.5082

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	28 (70.0)	32 (72.7)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 42.0)	15.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (16.0, NE)	48.0 (42.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.943
95% CI for the HR		(0.5623 , 1.5818)
p-value for the HR		0.8242

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.7.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	8 (61.5)	13 (81.3)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 16.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	16.0 (15.0, NE)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	NE (16.0, NE)	15.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.739
95% CI for the HR		(0.7095 , 4.2607)
p-value for the HR		0.2264

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	47 (75.8)	46 (76.7)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.5 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (15.0 , 43.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	46.0 (43.0 , 54.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.810
95% CI for the HR		(0.5359 , 1.2229)
p-value for the HR		0.3155

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.7.2.2 .2 .2 .5 BMI

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	14 (66.7)	11 (84.6)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.5 (4.0 , 45.0)	15.0 (4.0 , 17.0)
75th percentile - Q3 (95% CI)	45.0 (16.0, NE)	17.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.466
95% CI for the HR		(0.6359 , 3.3806)
p-value for the HR		0.3693

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	16 (80.0)	16 (76.2)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	5.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 45.0)	15.0 (5.0 , 45.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.945
95% CI for the HR		(0.4647 , 1.9208)
p-value for the HR		0.8753

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	25 (73.5)	32 (76.2)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	48.0 (42.0 , 54.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.778
95% CI for the HR		(0.4516 , 1.3389)
p-value for the HR		0.3642

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.7.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	24 (75.0)	28 (87.5)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 16.0)	15.0 (4.0 , 16.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	43.0 (15.0 , 48.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.049
95% CI for the HR		(0.6011 , 1.8302)
p-value for the HR		0.8665

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	31 (72.1)	31 (70.5)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 44.0)	15.0 (15.0 , 46.0)
75th percentile - Q3 (95% CI)	45.0 (16.0, NE)	48.0 (42.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.824
95% CI for the HR		(0.4982 , 1.3633)
p-value for the HR		0.4514

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.7.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	9 (90.0)	6 (60.0)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	15.0 (3.0, NE)
50th percentile - median (95% CI)	9.5 (3.0 , 16.0)	45.0 (3.0, NE)
75th percentile - Q3 (95% CI)	16.0 (4.0, NE)	48.0 (42.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.398
95% CI for the HR		(0.0998 , 1.5909)
p-value for the HR		0.1927

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	46 (70.8)	53 (80.3)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	5.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 16.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	45.0 (17.0, NE)	45.0 (16.0 , 48.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.051
95% CI for the HR		(0.7041 , 1.5691)
p-value for the HR		0.8074

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.7.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	44 (74.6)	52 (78.8)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 16.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	45.0 (16.0, NE)	46.0 (17.0 , 54.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.912
95% CI for the HR		(0.6055 , 1.3732)
p-value for the HR		0.6586

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-resp15-tte-201-by.sas:t-sf36-vs-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	11 (68.8)	7 (70.0)
Time to first Vitality Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	15.0 (3.0 , 18.0)
50th percentile - median (95% CI)	15.0 (4.0 , 45.0)	16.5 (3.0, NE)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	48.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.175
95% CI for the HR		(0.3001 , 4.5991)
p-value for the HR		0.8170

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

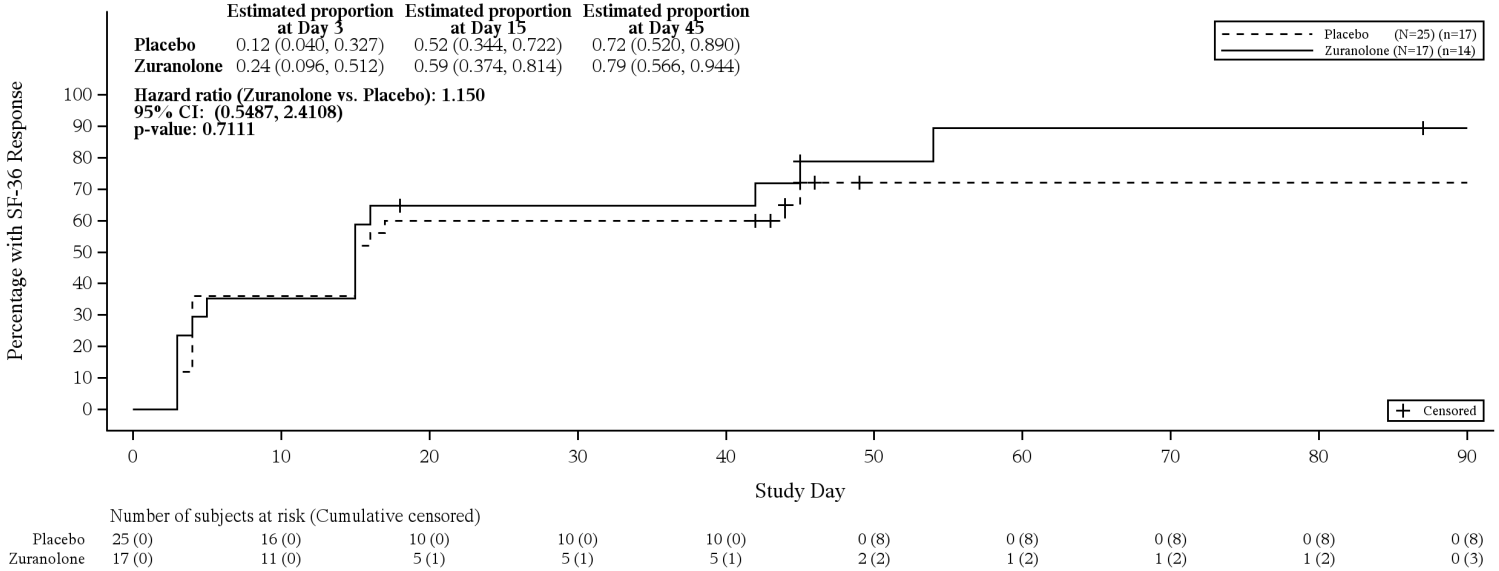
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2.7.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

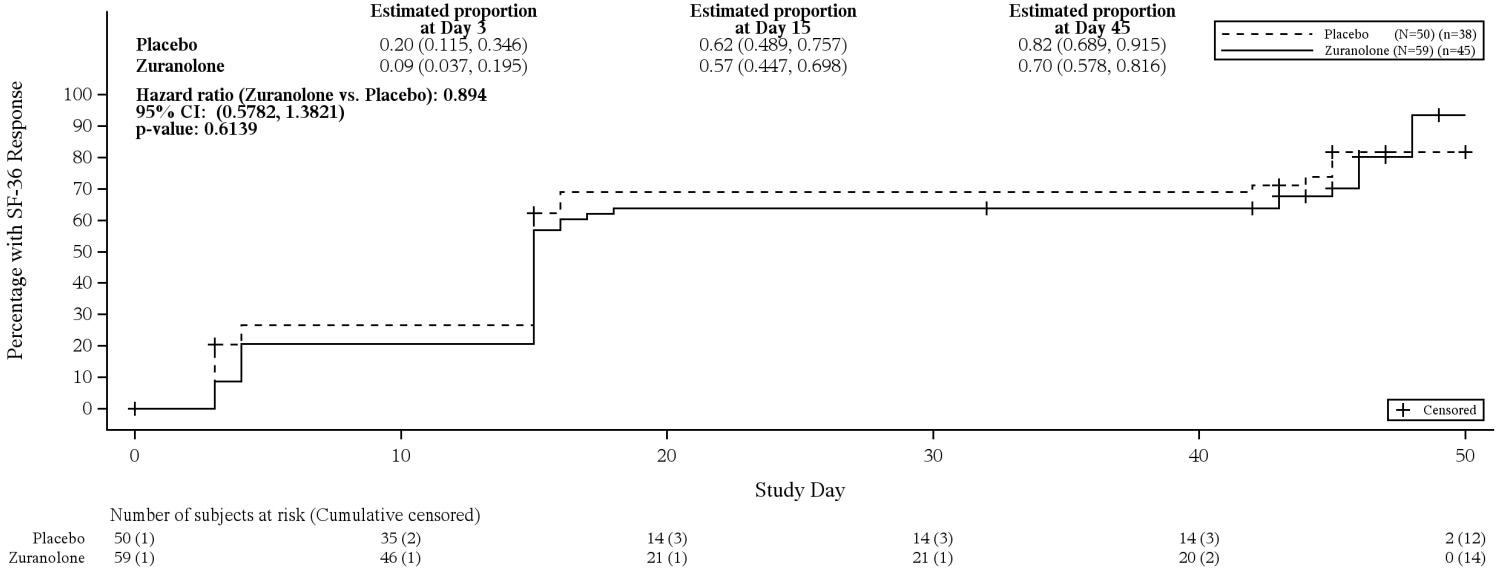
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

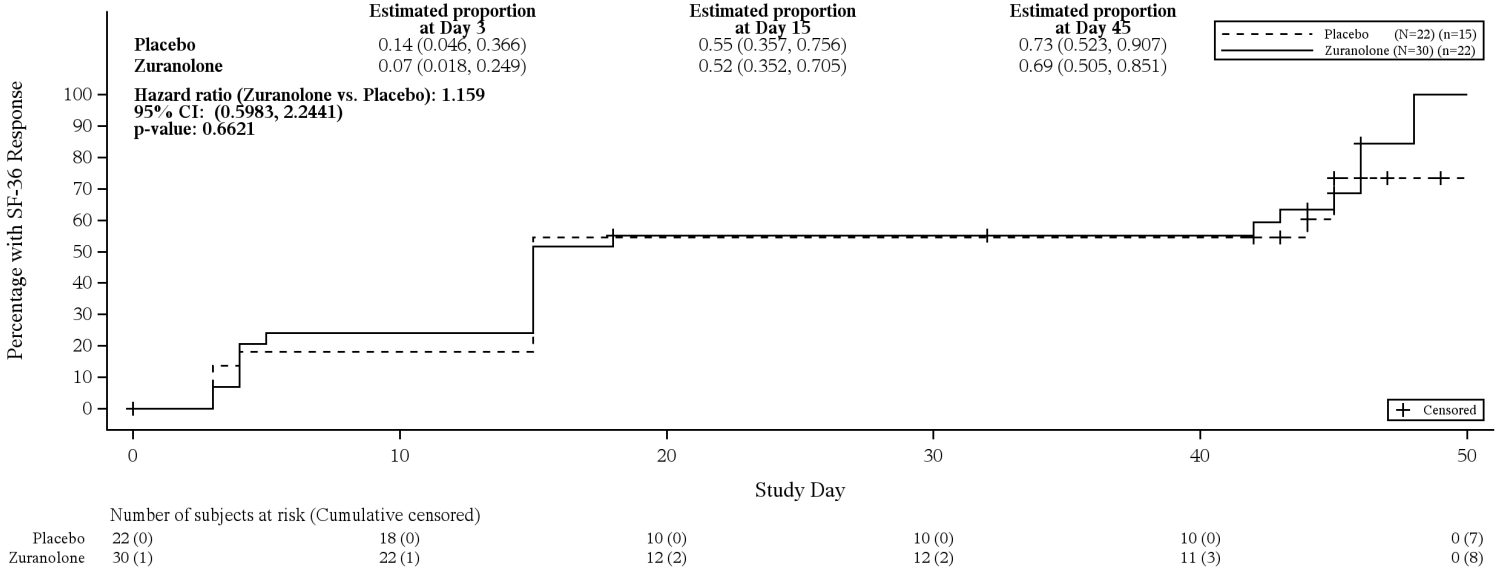
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	18 (0)	10 (0)	10 (0)	10 (0)	0 (7)
Zuranolone	30 (1)	22 (1)	12 (2)	12 (2)	11 (3)	0 (8)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

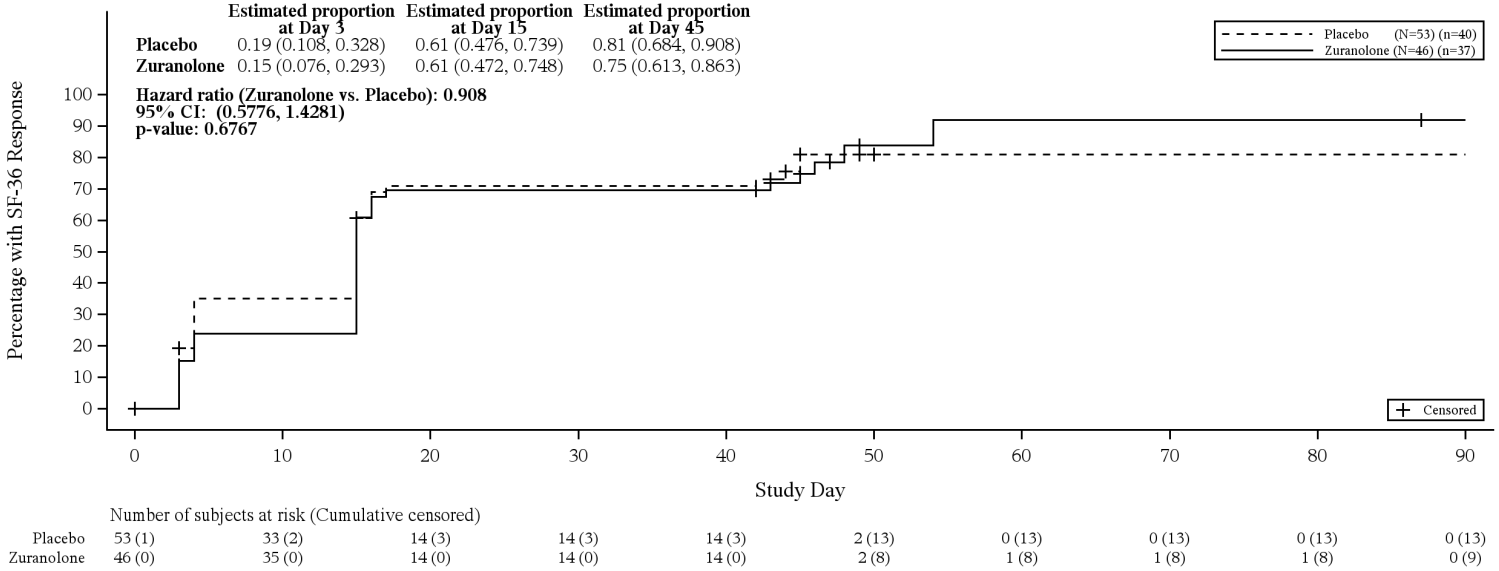
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

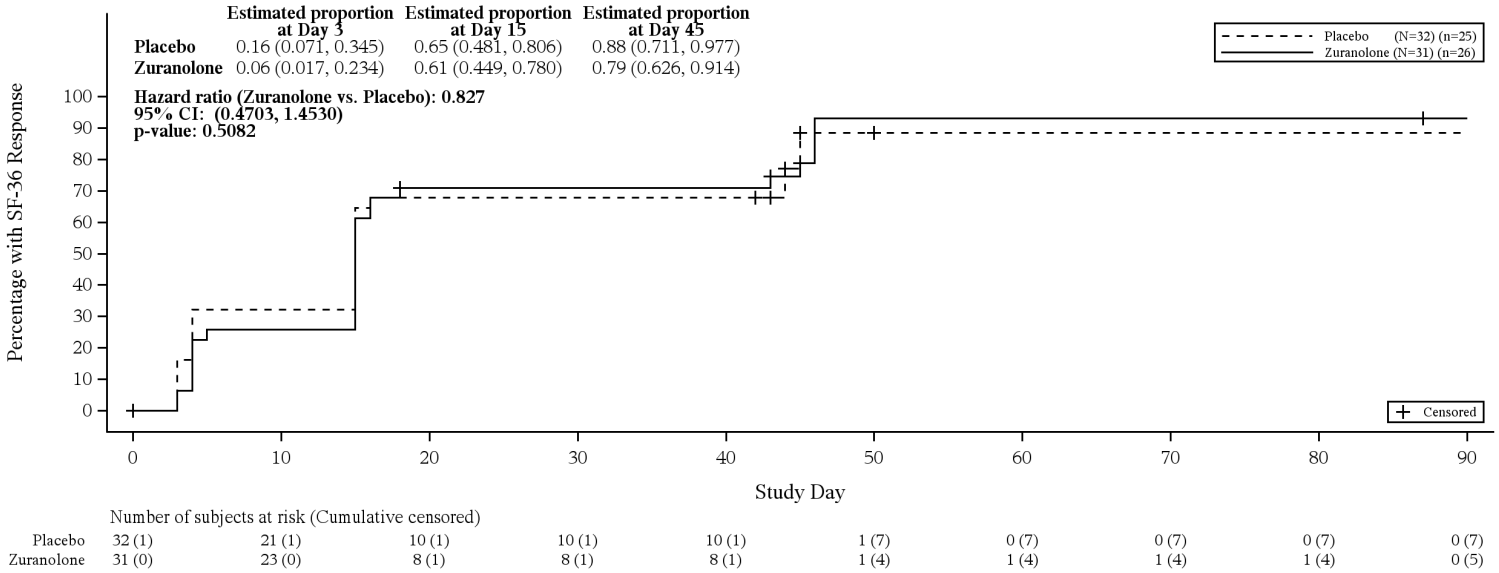
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

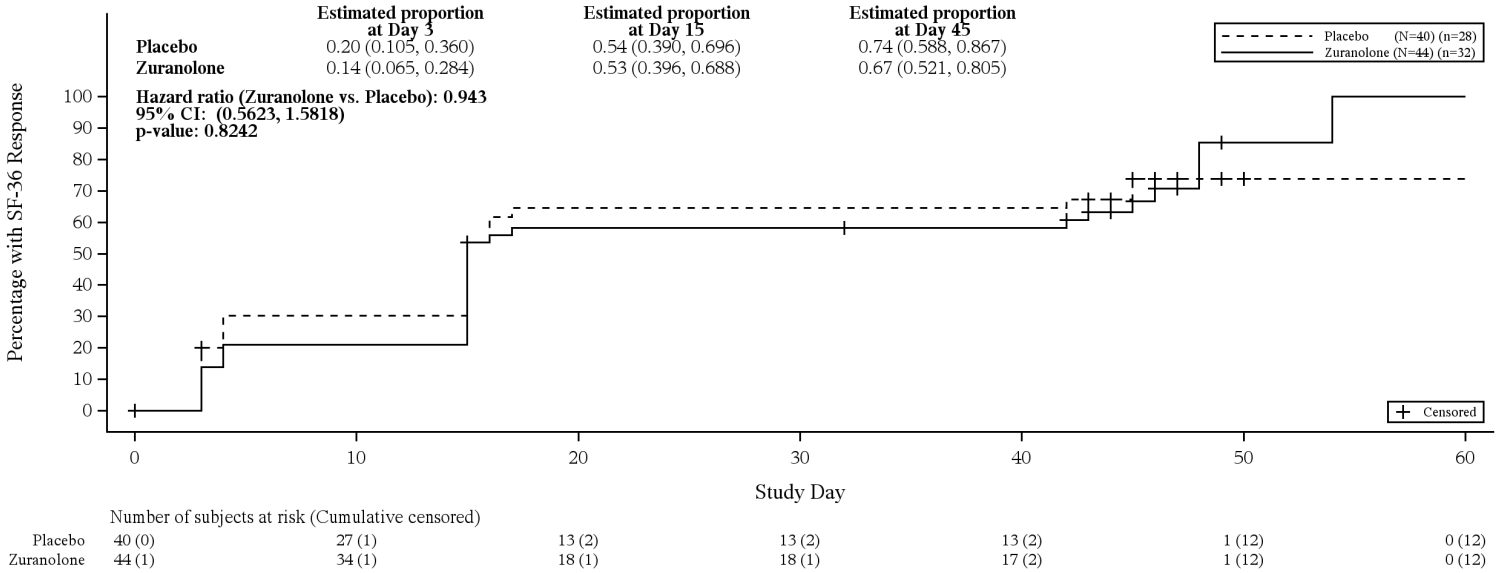
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

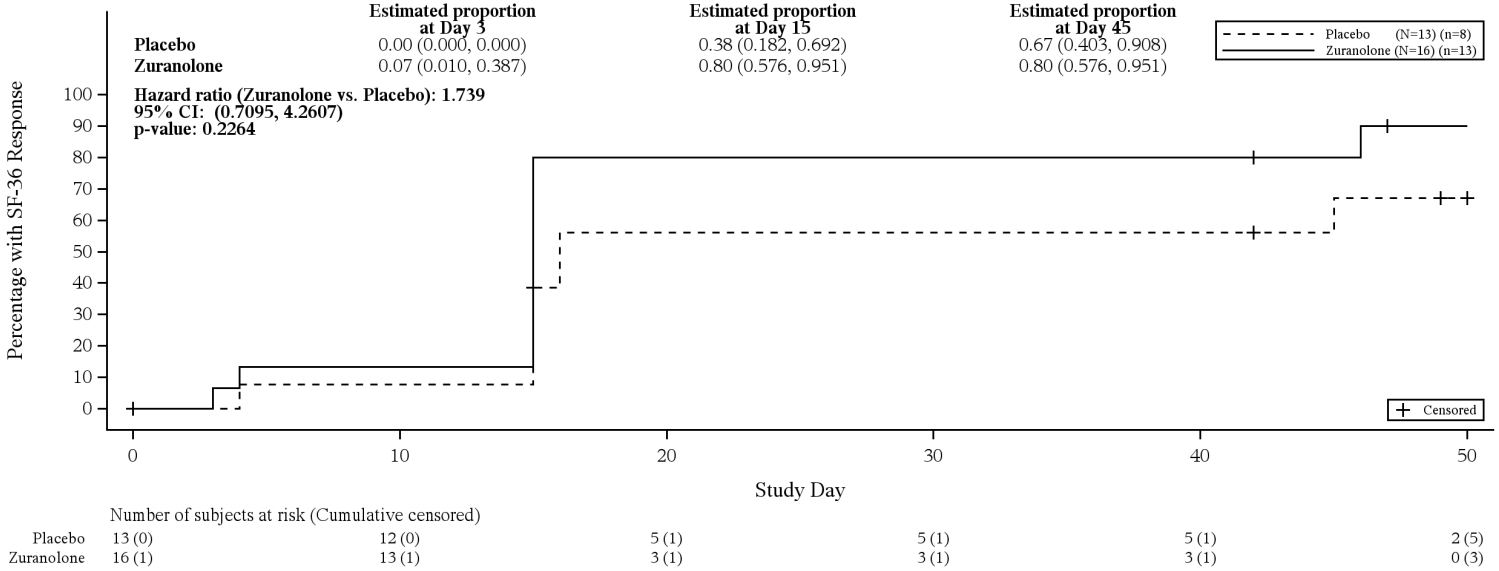
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

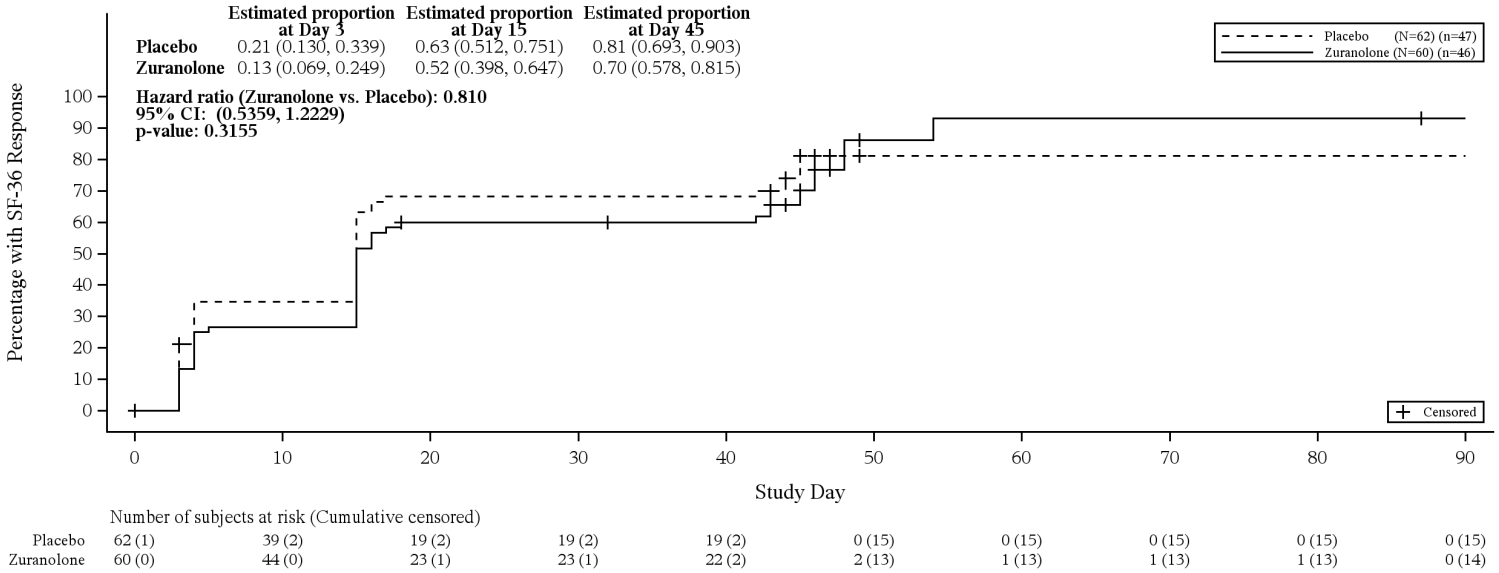
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

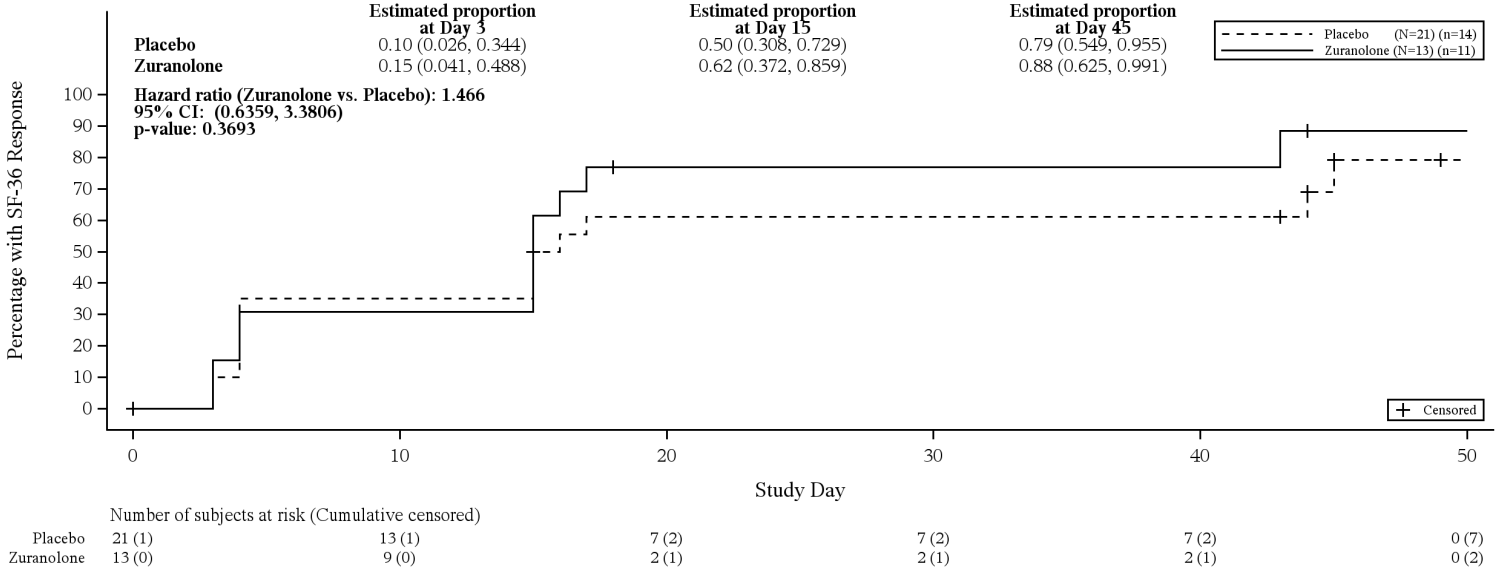
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

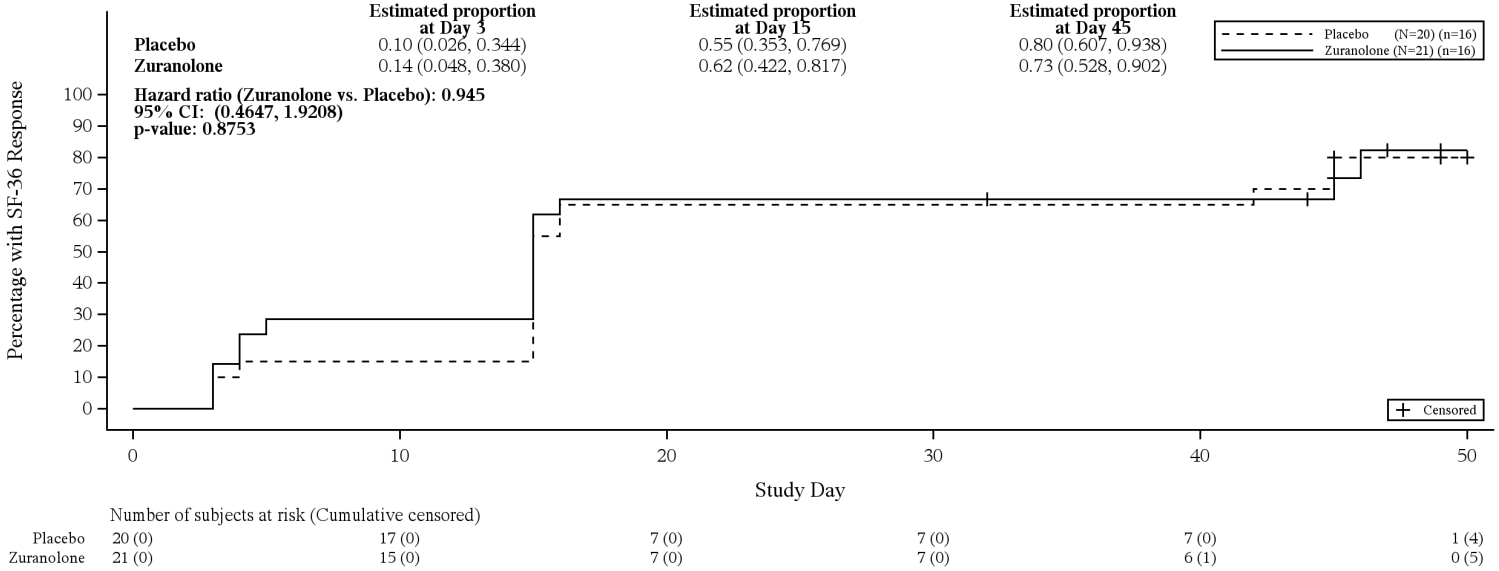
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Number of subjects at risk (Cumulative censored)

Placebo	20 (0)	17 (0)	7 (0)	7 (0)	7 (0)	1 (4)
Zuranolone	21 (0)	15 (0)	7 (0)	7 (0)	6 (1)	0 (5)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

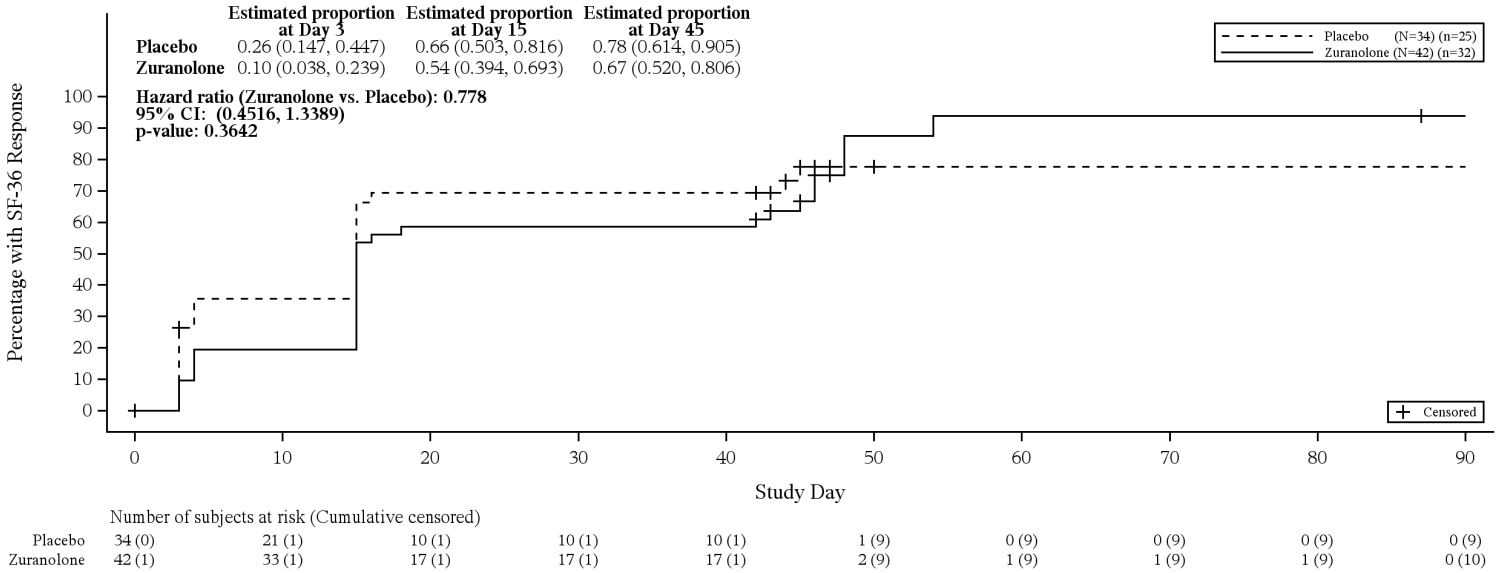
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

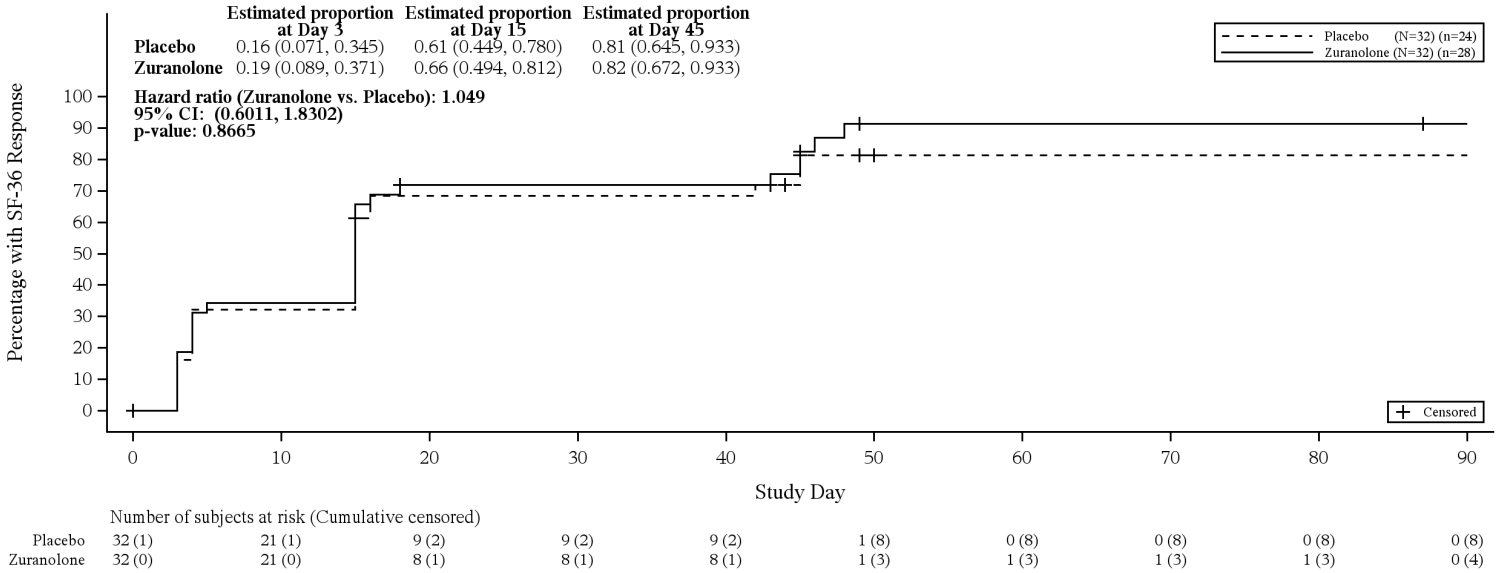
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

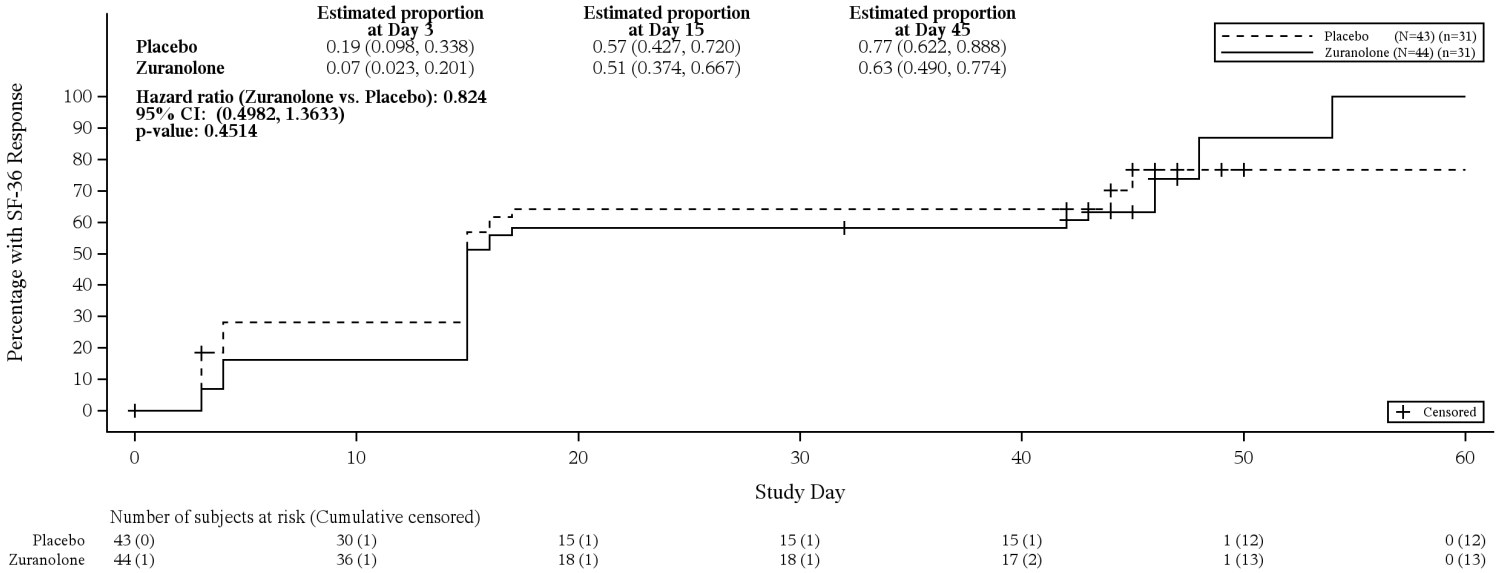
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

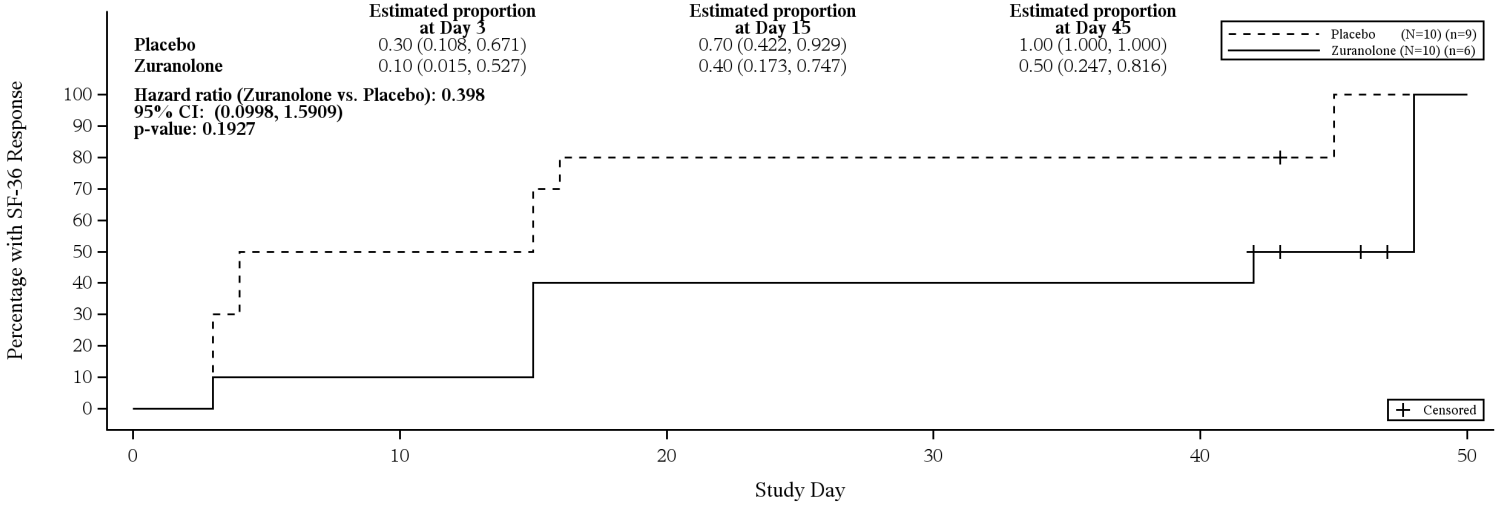
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Number of subjects at risk (Cumulative censored)

Placebo	10 (0)	5 (0)	2 (0)	2 (0)	2 (0)	0 (1)
Zuranolone	10 (0)	9 (0)	6 (0)	6 (0)	6 (0)	0 (4)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

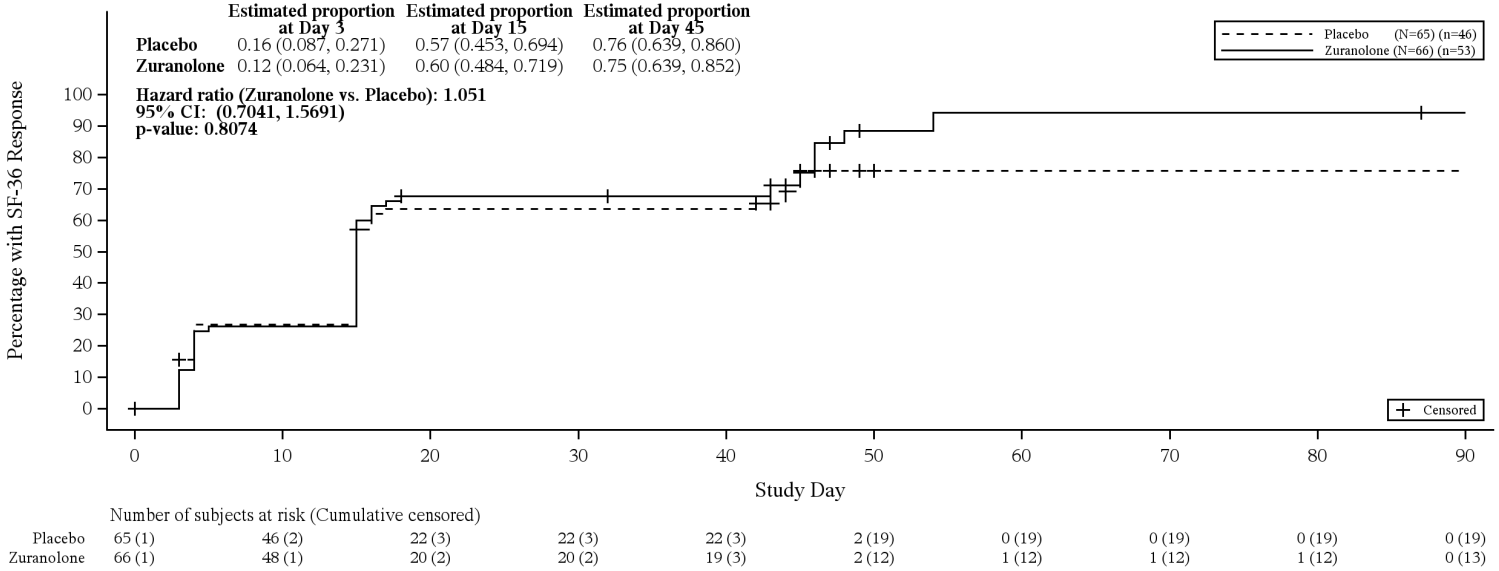
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

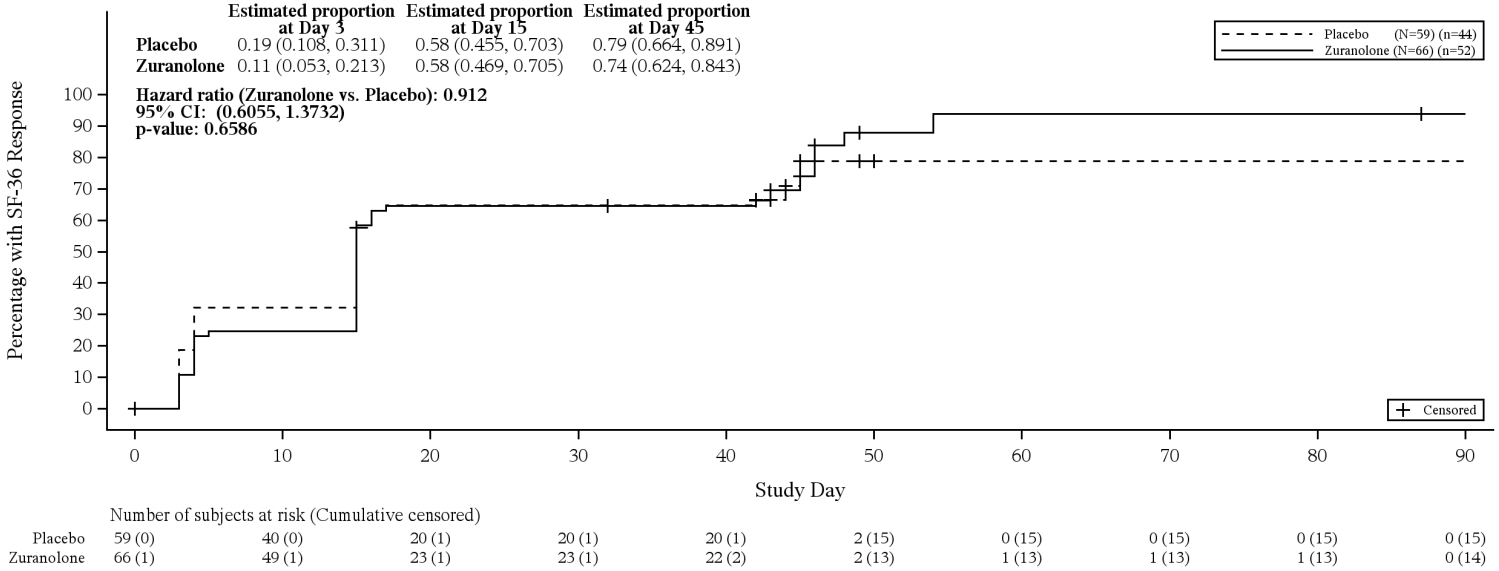
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

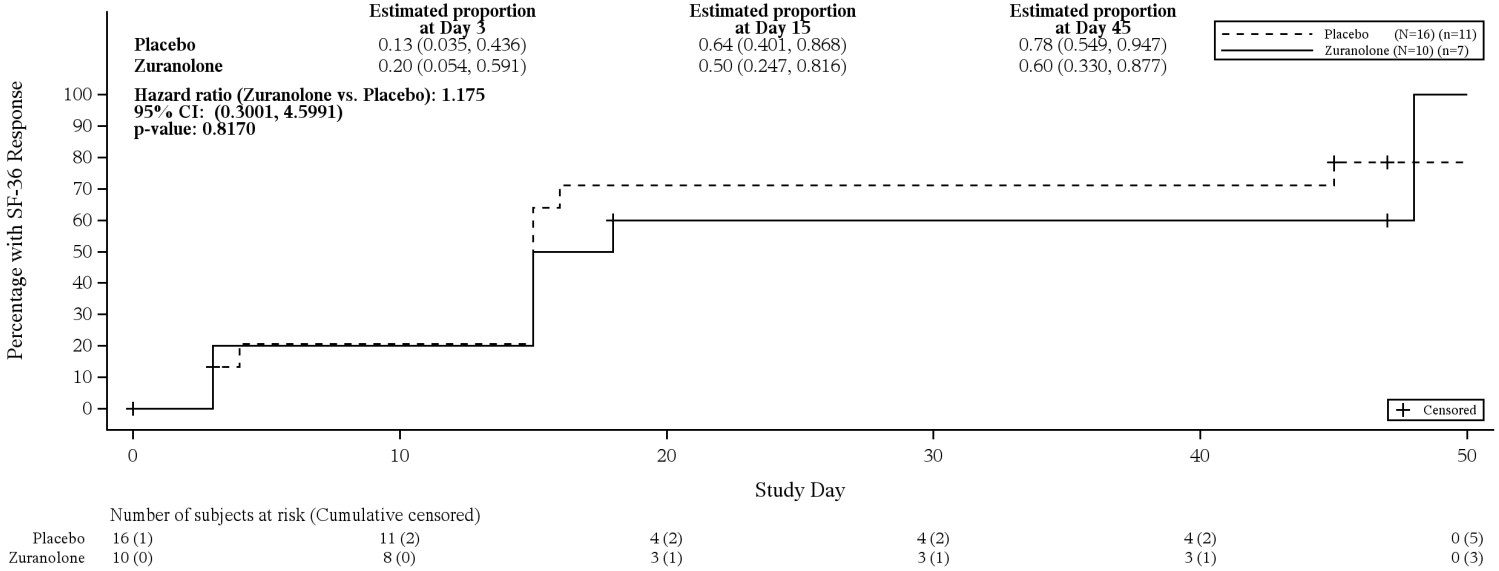
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 17 of 17

History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-vs-resp15-tte-201-by.sas:f-sf36-vs-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

2.7.3 Verschlechterung

2.7.3.1 Responder-Analysen

2.7.3.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Vitality Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with worsening, n (%) [2]	3 (4.0)	1 (1.3)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.035, 3.092)
p-value for RR		0.3307
OR - Odds Ratio (Zuranolone vs. Placebo)		0.32
95% CI for the OR		(0.033, 3.148)
p-value for OR		0.3286
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.078, 0.024)
p-value for ARR		0.3043

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Vitality subscale score worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-vs-wors15-201-ovr.sas:t-sf36-vs-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	2 (2.7)	0
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.20
95% CI for the RR		(0.010, 4.044)
p-value for RR		0.2923
OR - Odds Ratio (Zuranolone vs. Placebo)		0.19
95% CI for the OR		(0.009, 4.070)
p-value for OR		0.2897
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.070, 0.018)
p-value for ARR		0.2388

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing SF-36 Vitality subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Vitality subscale score worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-vs-wors15-201-ovr.sas:t-sf36-vs-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.7.3.1 .2 Subgruppen

2.7.3.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Vitality Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	3 (4.0)	1 (1.3)	
Number of subjects with response at Day 45, n (%)	2 (2.7)	0	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	2/25 (8.0)	1/17 (5.9)	
25 - 45, n / N (%)	1/50 (2.0)	0/59	
Day 45			
18 - 24, n / N (%)	1/25 (4.0)	0/17	
25 - 45, n / N (%)	1/50 (2.0)	0/59	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-wors15-201-int.sas:t-sf36-vs-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	1/22 (4.5)	1/30 (3.3)	
>=28, n / N (%)	2/53 (3.8)	0/46	
Day 45			
<28, n / N (%)	0/22	0/30	
>=28, n / N (%)	2/53 (3.8)	0/46	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	2/32 (6.3)	1/31 (3.2)	
White, n / N (%)	1/40 (2.5)	0/44	
Day 45			
Black or African American, n / N (%)	1/32 (3.1)	0/31	
White, n / N (%)	1/40 (2.5)	0/44	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-wors15-201-int.sas:t-sf36-vs-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	1/13 (7.7)	0/16	
No, n / N (%)	2/62 (3.2)	1/60 (1.7)	
Day 45			
Yes, n / N (%)	1/13 (7.7)	0/16	
No, n / N (%)	1/62 (1.6)	0/60	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-wors15-201-int.sas:t-sf36-vs-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	1/21 (4.8)	1/13 (7.7)	
25-29.9, n / N (%)	1/20 (5.0)	0/21	
>=30, n / N (%)	1/34 (2.9)	0/42	
Day 45			
<=24.9, n / N (%)	1/21 (4.8)	0/13	
25-29.9, n / N (%)	1/20 (5.0)	0/21	
>=30, n / N (%)	0/34	0/42	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-wors15-201-int.sas:t-sf36-vs-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	0/32	1/32 (3.1)	
Postpartum, n / N (%)	3/43 (7.0)	0/44	
Day 45			
3rd Trimester, n / N (%)	0/32	0/32	
Postpartum, n / N (%)	2/43 (4.7)	0/44	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	3/65 (4.6)	1/66 (1.5)	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	2/65 (3.1)	0/66	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-wors15-201-int.sas:t-sf36-vs-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Vitality Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 6 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	3/59 (5.1)	0/66	
Recurrent Episode, n / N (%)	0/16	1/10 (10.0)	
Day 45			
1st Episode, n / N (%)	2/59 (3.4)	0/66	
Recurrent Episode, n / N (%)	0/16	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	3/67 (4.5)	1/66 (1.5)	
Day 45			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	2/67 (3.0)	0/66	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-wors15-201-int.sas:t-sf36-vs-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

2.7.3.1 .2 .2 Subgruppenanalysen

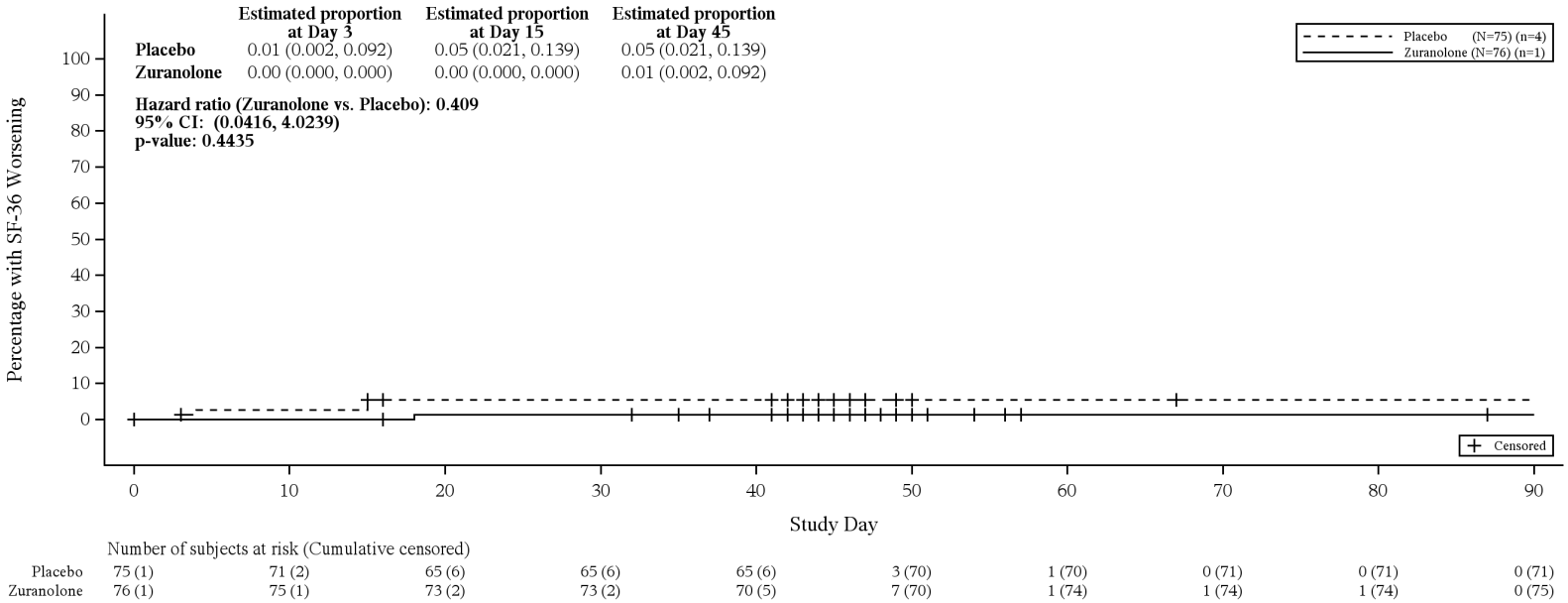
Nicht zutreffend.

2.7.3.2 TTE-Analysen

2.7.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Vitality Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-vs-wors15-tte-201-ovr.sas:f-sf36-vs-wors15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	4 (5.3)	1 (1.3)
Time to first Vitality Subscale worsening (days) [3]		
25th percentile - Q1 (95% CI)	NE (NE, NE)	NE (NE, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.409
95% CI for the HR		(0.0416 , 4.0239)
p-value for the HR		0.4435

NOTE 1: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) worsening. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-vs-wors15-tte-201-ovr.sas:t-sf36-vs-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.7.3.2 .2 Subgruppen

2.7.3.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	4 (5.3)	1 (1.3)	
Age Group (years)			
18 - 24, n / N (%)	2/25 (8.0)	1/17 (5.9)	NA
25 - 45, n / N (%)	2/50 (4.0)	0/59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	1/22 (4.5)	1/30 (3.3)	NA
>=28, n / N (%)	3/53 (5.7)	0/46	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	3/32 (9.4)	1/31 (3.2)	NA
White, n / N (%)	1/40 (2.5)	0/44	
Antidepressant Use at Baseline			
Yes, n / N (%)	1/13 (7.7)	0/16	NA
No, n / N (%)	3/62 (4.8)	1/60 (1.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-wors15-tte-201-int.sas:t-sf36-vs-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Vitality Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	2/21 (9.5)	1/13 (7.7)	NA(a)
25-29.9, n / N (%)	1/20 (5.0)	0/21	NA(b)
>=30, n / N (%)	1/34 (2.9)	0/42	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	0/32	1/32 (3.1)	NA
Postpartum, n / N (%)	4/43 (9.3)	0/44	
Family History of PPD			
Yes, n / N (%)	0/10	0/10	NA
No/Unknown, n / N (%)	4/65 (6.2)	1/66 (1.5)	
History of PPD			
1st Episode, n / N (%)	4/59 (6.8)	0/66	NA
Recurrent Episode, n / N (%)	0/16	1/10 (10.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/8	0/10	NA
>=20, n / N (%)	4/67 (6.0)	1/66 (1.5)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-vs-wors15-tte-201-int.sas:t-sf36-vs-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.7.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

2.7.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

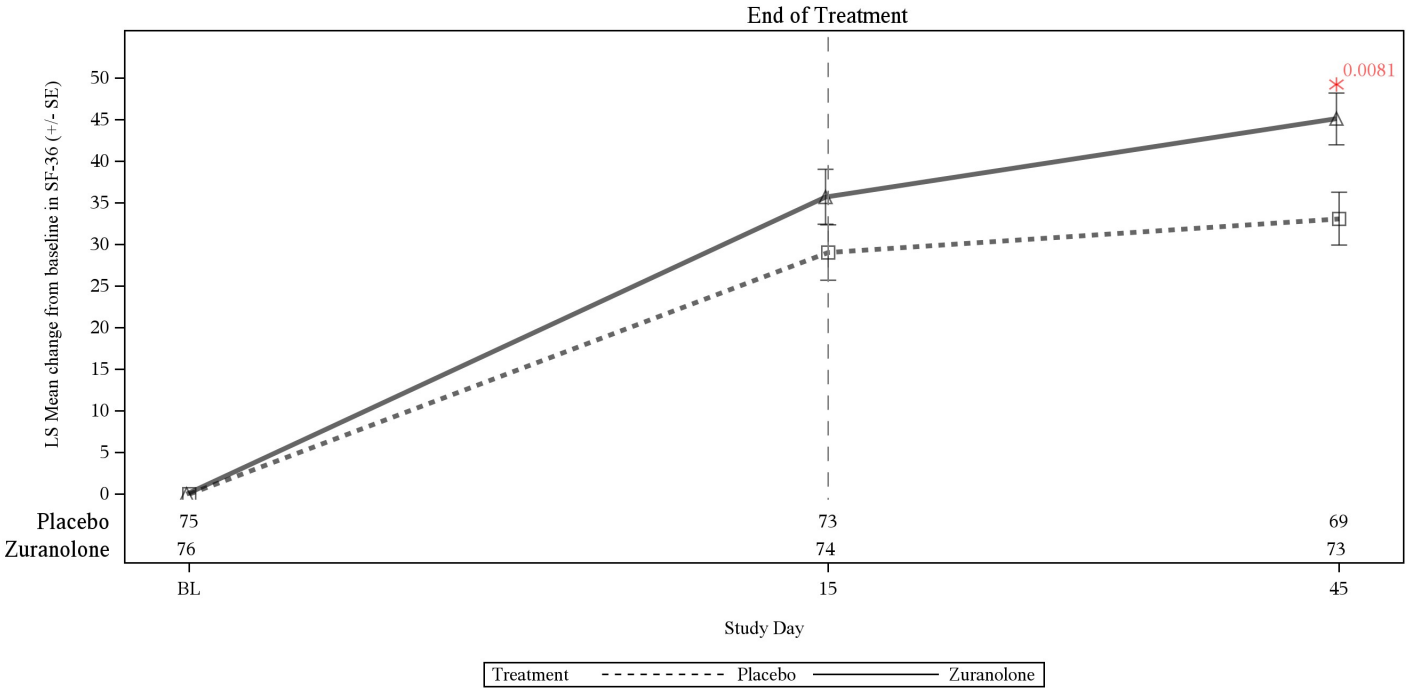
2.8 soziale Funktionsfähigkeit

2.8.1 MMRM

2.8.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-ovr.sas:f-sf36-sf-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	29.06 (3.339)	35.73 (3.312)
95% CI for the LS Mean	22.46, 35.66	29.18, 42.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.67 (4.705)
95% CI for the LS Mean		-2.63, 15.97
p-value		0.1586
Hedges' g (Zuranolone vs. Placebo)		0.233
95% CI for Hedges' g		-0.0918, 0.5570
Day 45		
n	69	73
LS Mean (SE)	33.11 (3.196)	45.11 (3.119)
95% CI for the LS Mean	26.79, 39.42	38.94, 51.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		12.00 (4.469)
95% CI for the LS Mean		3.16, 20.83
p-value		0.0081
Hedges' g (Zuranolone vs. Placebo)		0.448
95% CI for Hedges' g		0.1151, 0.7815

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-ovr.sas:t-sf36-sf-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.8.1.2 Subgruppen

2.8.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.6154
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.1777
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.6538
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.8390
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-int.sas:t-sf36-sf-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.1416(a)
25-29.9	20	21	0.1544(b)
>=30	34	42	0.8197(c)
Onset of PPD			
3rd Trimester	32	32	0.1865
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.0990
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.4480
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-int.sas:t-sf36-sf-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

2.8.1.2 .2 Subgruppenanalysen

2.8.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	24.05 (5.276)	34.04 (6.412)
95% CI for the LS Mean	13.38, 34.73	21.07, 47.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.99 (8.318)
95% CI for the LS Mean		-6.84, 26.82
p-value		0.2371
Hedges' g (Zuranolone vs. Placebo)		0.370
95% CI for Hedges' g		-0.2508, 0.9916
Day 45		
n	25	16
LS Mean (SE)	25.55 (5.452)	40.61 (6.798)
95% CI for the LS Mean	14.50, 36.60	26.84, 54.38
Difference (Zuranolone - Placebo)		
LS Mean (SE)		15.05 (8.723)
95% CI for the LS Mean		-2.62, 32.73
p-value		0.0927
Hedges' g (Zuranolone vs. Placebo)		0.542
95% CI for Hedges' g		-0.0966, 1.1801

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Age Group: 217-PPD-201B - ITT population

Page: 2 of 2

Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	31.34 (4.293)	36.41 (3.929)
95% CI for the LS Mean	22.83, 39.86	28.62, 44.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.07 (5.821)
95% CI for the LS Mean		-6.48, 16.62
p-value		0.3859
Hedges' g (Zuranolone vs. Placebo)		0.169
95% CI for Hedges' g		-0.2153, 0.5540
Day 45		
n	44	57
LS Mean (SE)	36.93 (3.985)	46.76 (3.542)
95% CI for the LS Mean	29.03, 44.84	39.74, 53.79
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.83 (5.337)
95% CI for the LS Mean		-0.76, 20.42
p-value		0.0684
Hedges' g (Zuranolone vs. Placebo)		0.367
95% CI for Hedges' g		-0.0297, 0.7634

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.8.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 2

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	35.46 (6.314)	34.26 (5.564)
95% CI for the LS Mean	22.74, 48.18	23.05, 45.47
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.20 (8.498)
95% CI for the LS Mean		-18.32, 15.92
p-value		0.8883
Hedges' g (Zuranolone vs. Placebo)		-0.040
95% CI for Hedges' g		-0.5981, 0.5188
Day 45		
n	22	28
LS Mean (SE)	40.57 (5.534)	45.46 (4.868)
95% CI for the LS Mean	29.43, 51.71	35.66, 55.26
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.89 (7.458)
95% CI for the LS Mean		-10.12, 19.90
p-value		0.5153
Hedges' g (Zuranolone vs. Placebo)		0.184
95% CI for Hedges' g		-0.3757, 0.7434

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	26.08 (3.994)	36.67 (4.208)
95% CI for the LS Mean	18.15, 34.01	28.31, 45.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		10.58 (5.806)
95% CI for the LS Mean		-0.94, 22.11
p-value		0.0715
Hedges' g (Zuranolone vs. Placebo)		0.368
95% CI for Hedges' g		-0.0341, 0.7696
Day 45		
n	47	45
LS Mean (SE)	29.51 (3.974)	45.10 (4.090)
95% CI for the LS Mean	21.62, 37.41	36.98, 53.23
Difference (Zuranolone - Placebo)		
LS Mean (SE)		15.59 (5.710)
95% CI for the LS Mean		4.25, 26.93
p-value		0.0076
Hedges' g (Zuranolone vs. Placebo)		0.565
95% CI for Hedges' g		0.1478, 0.9815

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.8.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	32.81 (5.547)	41.40 (5.546)
95% CI for the LS Mean	21.71, 43.92	30.30, 52.50
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.58 (7.849)
95% CI for the LS Mean		-7.13, 24.29
p-value		0.2787
Hedges' g (Zuranolone vs. Placebo)		0.274
95% CI for Hedges' g		-0.2259, 0.7744
Day 45		
n	30	30
LS Mean (SE)	32.89 (5.048)	47.60 (5.048)
95% CI for the LS Mean	22.78, 43.01	37.49, 57.71
Difference (Zuranolone - Placebo)		
LS Mean (SE)		14.71 (7.145)
95% CI for the LS Mean		0.40, 29.02
p-value		0.0442
Hedges' g (Zuranolone vs. Placebo)		0.525
95% CI for Hedges' g		0.0099, 1.0393

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	26.58 (4.267)	32.63 (4.094)
95% CI for the LS Mean	18.08, 35.08	24.47, 40.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.05 (5.916)
95% CI for the LS Mean		-5.73, 17.84
p-value		0.3096
Hedges' g (Zuranolone vs. Placebo)		0.225
95% CI for Hedges' g		-0.2119, 0.6625
Day 45		
n	36	42
LS Mean (SE)	34.78 (4.170)	43.38 (3.907)
95% CI for the LS Mean	26.48, 43.08	35.60, 51.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.60 (5.719)
95% CI for the LS Mean		-2.78, 19.99
p-value		0.1366
Hedges' g (Zuranolone vs. Placebo)		0.338
95% CI for Hedges' g		-0.1100, 0.7866

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.8.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	24.44 (7.207)	35.96 (6.659)
95% CI for the LS Mean	9.61, 39.28	22.25, 49.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.52 (10.029)
95% CI for the LS Mean		-9.12, 32.15
p-value		0.2615
Hedges' g (Zuranolone vs. Placebo)		0.422
95% CI for Hedges' g		-0.3284, 1.1733
Day 45		
n	11	15
LS Mean (SE)	35.48 (7.247)	43.46 (6.414)
95% CI for the LS Mean	20.53, 50.43	30.17, 56.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.98 (9.894)
95% CI for the LS Mean		-12.46, 28.42
p-value		0.4279
Hedges' g (Zuranolone vs. Placebo)		0.310
95% CI for Hedges' g		-0.4725, 1.0927

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	30.23 (3.803)	35.51 (3.830)
95% CI for the LS Mean	22.70, 37.77	27.92, 43.10
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.28 (5.420)
95% CI for the LS Mean		-5.46, 16.01
p-value		0.3320
Hedges' g (Zuranolone vs. Placebo)		0.177
95% CI for Hedges' g		-0.1826, 0.5375
Day 45		
n	58	58
LS Mean (SE)	33.08 (3.611)	45.38 (3.612)
95% CI for the LS Mean	25.93, 40.23	38.23, 52.54
Difference (Zuranolone - Placebo)		
LS Mean (SE)		12.30 (5.129)
95% CI for the LS Mean		2.14, 22.46
p-value		0.0181
Hedges' g (Zuranolone vs. Placebo)		0.442
95% CI for Hedges' g		0.0741, 0.8109

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.8.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	26.02 (6.749)	42.38 (8.368)
95% CI for the LS Mean	12.24, 39.81	25.29, 59.48
Difference (Zuranolone - Placebo)		
LS Mean (SE)		16.36 (10.748)
95% CI for the LS Mean		-5.59, 38.32
p-value		0.1385
Hedges' g (Zuranolone vs. Placebo)		0.529
95% CI for Hedges' g		-0.1807, 1.2389
Day 45		
n	18	12
LS Mean (SE)	22.82 (6.498)	49.83 (7.984)
95% CI for the LS Mean	9.51, 36.13	33.47, 66.19
Difference (Zuranolone - Placebo)		
LS Mean (SE)		27.01 (10.300)
95% CI for the LS Mean		5.90, 48.11
p-value		0.0140
Hedges' g (Zuranolone vs. Placebo)		0.951
95% CI for Hedges' g		0.1818, 1.7199

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	33.59 (6.826)	38.37 (6.754)
95% CI for the LS Mean	19.72, 47.46	24.66, 52.08
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.78 (9.610)
95% CI for the LS Mean		-14.73, 24.30
p-value		0.6218
Hedges' g (Zuranolone vs. Placebo)		0.154
95% CI for Hedges' g		-0.4664, 0.7750
Day 45		
n	20	20
LS Mean (SE)	41.71 (6.319)	45.98 (6.251)
95% CI for the LS Mean	28.90, 54.53	33.32, 58.65
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.27 (8.897)
95% CI for the LS Mean		-13.76, 22.30
p-value		0.6342
Hedges' g (Zuranolone vs. Placebo)		0.149
95% CI for Hedges' g		-0.4719, 0.7694

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	28.00 (4.809)	32.31 (4.312)
95% CI for the LS Mean	18.41, 37.59	23.71, 40.91
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.31 (6.478)
95% CI for the LS Mean		-8.61, 17.23
p-value		0.5079
Hedges' g (Zuranolone vs. Placebo)		0.154
95% CI for Hedges' g		-0.3050, 0.6130
Day 45		
n	31	41
LS Mean (SE)	33.26 (4.537)	43.29 (3.962)
95% CI for the LS Mean	24.21, 42.30	35.38, 51.19
Difference (Zuranolone - Placebo)		
LS Mean (SE)		10.03 (6.045)
95% CI for the LS Mean		-2.03, 22.09
p-value		0.1016
Hedges' g (Zuranolone vs. Placebo)		0.391
95% CI for Hedges' g		-0.0802, 0.8615

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.8.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	26.44 (5.383)	39.60 (5.296)
95% CI for the LS Mean	15.67, 37.21	29.00, 50.20
Difference (Zuranolone - Placebo)		
LS Mean (SE)		13.16 (7.557)
95% CI for the LS Mean		-1.96, 28.28
p-value		0.0869
Hedges' g (Zuranolone vs. Placebo)		0.433
95% CI for Hedges' g		-0.0663, 0.9330
Day 45		
n	29	30
LS Mean (SE)	33.69 (4.777)	51.71 (4.698)
95% CI for the LS Mean	24.12, 43.25	42.30, 61.12
Difference (Zuranolone - Placebo)		
LS Mean (SE)		18.02 (6.701)
95% CI for the LS Mean		4.60, 31.45
p-value		0.0094
Hedges' g (Zuranolone vs. Placebo)		0.691
95% CI for Hedges' g		0.1657, 1.2166

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	31.06 (4.295)	32.80 (4.283)
95% CI for the LS Mean	22.52, 39.61	24.28, 41.32
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.74 (6.076)
95% CI for the LS Mean		-10.36, 13.83
p-value		0.7757
Hedges' g (Zuranolone vs. Placebo)		0.062
95% CI for Hedges' g		-0.3660, 0.4896
Day 45		
n	40	43
LS Mean (SE)	32.81 (4.318)	40.52 (4.196)
95% CI for the LS Mean	24.22, 41.40	32.17, 48.87
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.70 (6.035)
95% CI for the LS Mean		-4.30, 19.71
p-value		0.2053
Hedges' g (Zuranolone vs. Placebo)		0.278
95% CI for Hedges' g		-0.1548, 0.7105

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.8.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	25.92 (8.736)	23.67 (8.774)
95% CI for the LS Mean	7.55, 44.29	5.23, 42.11
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.25 (12.545)
95% CI for the LS Mean		-28.57, 24.08
p-value		0.8599
Hedges' g (Zuranolone vs. Placebo)		-0.077
95% CI for Hedges' g		-0.9535, 0.8001
Day 45		
n	9	10
LS Mean (SE)	41.44 (5.929)	28.67 (5.617)
95% CI for the LS Mean	28.77, 54.12	16.55, 40.79
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-12.77 (8.518)
95% CI for the LS Mean		-31.02, 5.48
p-value		0.1558
Hedges' g (Zuranolone vs. Placebo)		-0.658
95% CI for Hedges' g		-1.5825, 0.2666

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	29.67 (3.650)	37.53 (3.615)
95% CI for the LS Mean	22.44, 36.89	30.38, 44.69
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.87 (5.144)
95% CI for the LS Mean		-2.32, 18.05
p-value		0.1288
Hedges' g (Zuranolone vs. Placebo)		0.270
95% CI for Hedges' g		-0.0797, 0.6192
Day 45		
n	60	63
LS Mean (SE)	31.80 (3.531)	47.61 (3.455)
95% CI for the LS Mean	24.81, 38.79	40.77, 54.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		15.81 (4.946)
95% CI for the LS Mean		6.02, 25.60
p-value		0.0018
Hedges' g (Zuranolone vs. Placebo)		0.573
95% CI for Hedges' g		0.2123, 0.9338

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.8.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	29.01 (3.818)	36.26 (3.657)
95% CI for the LS Mean	21.45, 36.57	29.02, 43.51
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.25 (5.307)
95% CI for the LS Mean		-3.26, 17.76
p-value		0.1744
Hedges' g (Zuranolone vs. Placebo)		0.245
95% CI for Hedges' g		-0.1100, 0.6001
Day 45		
n	55	64
LS Mean (SE)	31.61 (3.643)	45.80 (3.403)
95% CI for the LS Mean	24.40, 38.83	39.06, 52.54
Difference (Zuranolone - Placebo)		
LS Mean (SE)		14.19 (5.008)
95% CI for the LS Mean		4.27, 24.11
p-value		0.0054
Hedges' g (Zuranolone vs. Placebo)		0.518
95% CI for Hedges' g		0.1513, 0.8840

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	29.28 (7.549)	32.06 (8.992)
95% CI for the LS Mean	13.61, 44.94	13.40, 50.72
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.78 (12.387)
95% CI for the LS Mean		-22.88, 28.44
p-value		0.8244
Hedges' g (Zuranolone vs. Placebo)		0.090
95% CI for Hedges' g		-0.7221, 0.9017
Day 45		
n	14	9
LS Mean (SE)	39.10 (7.265)	40.46 (9.286)
95% CI for the LS Mean	23.94, 54.26	21.24, 59.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.36 (12.578)
95% CI for the LS Mean		-24.65, 27.37
p-value		0.9149
Hedges' g (Zuranolone vs. Placebo)		0.044
95% CI for Hedges' g		-0.7930, 0.8820

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

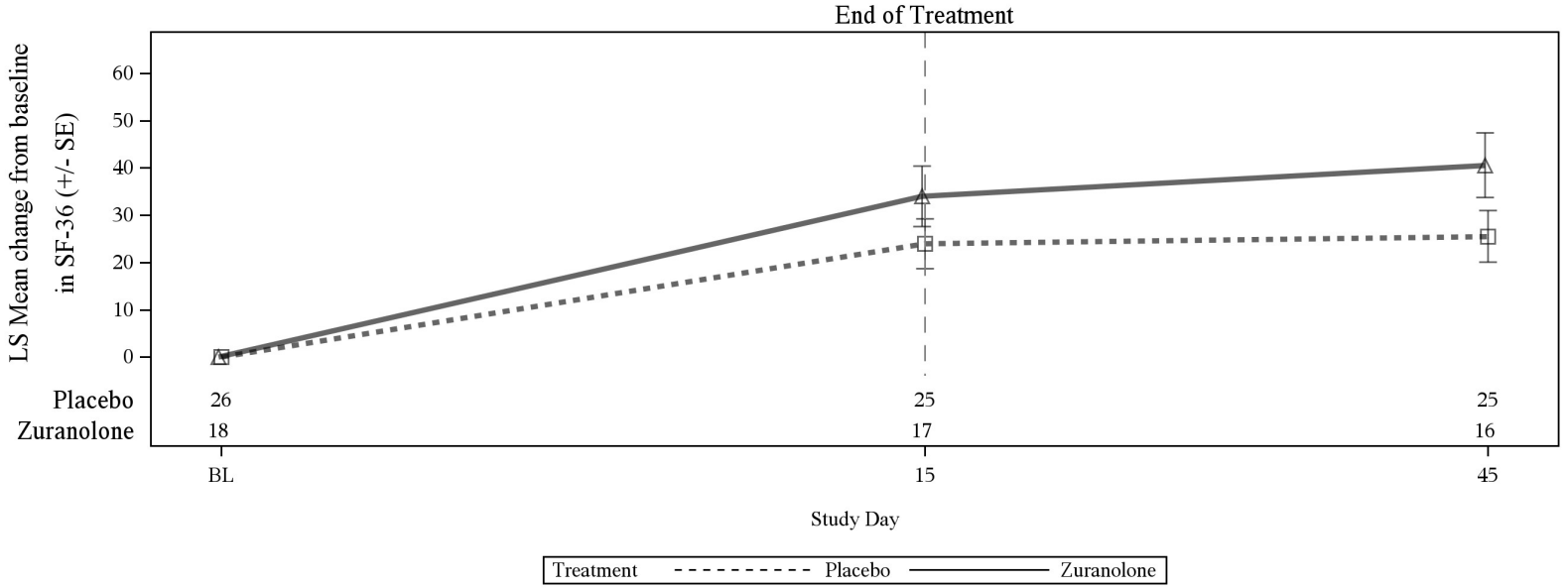
Source: biib125/v_a/germany_amnog/t-sf36-sf-mmrm-201-by.sas:t-sf36-sf-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.8.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

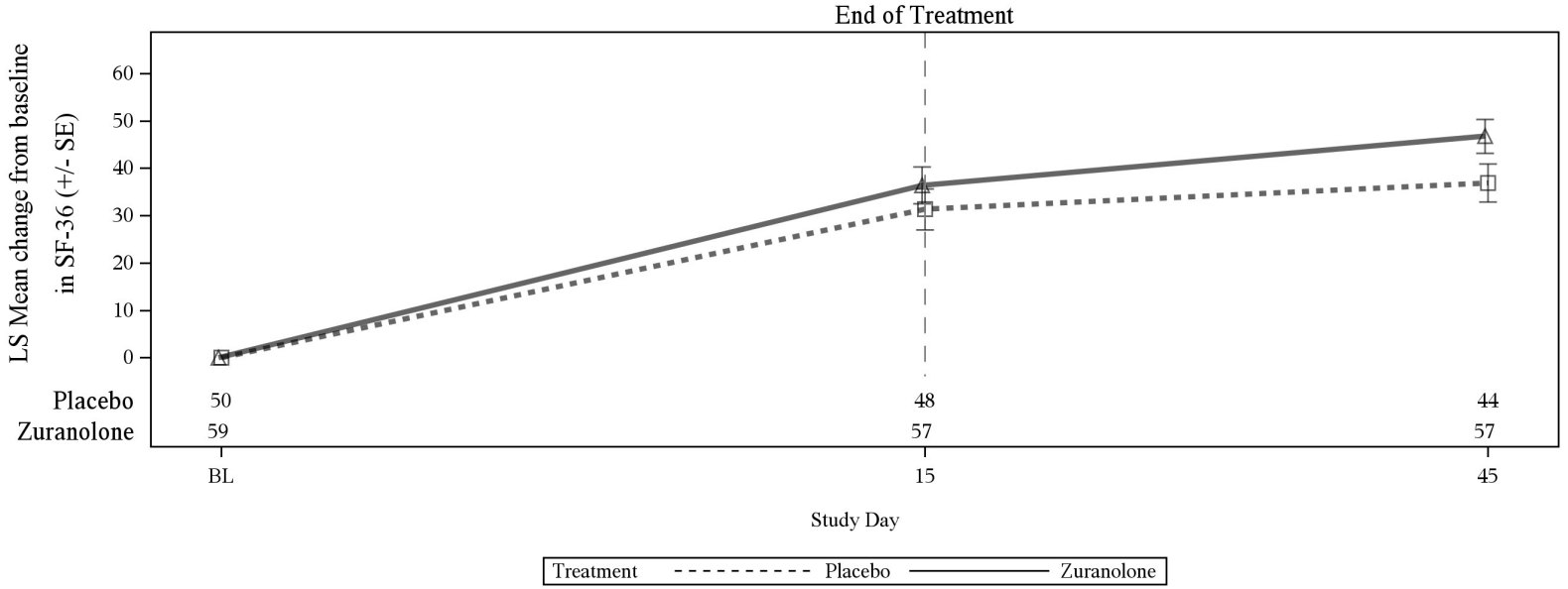
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

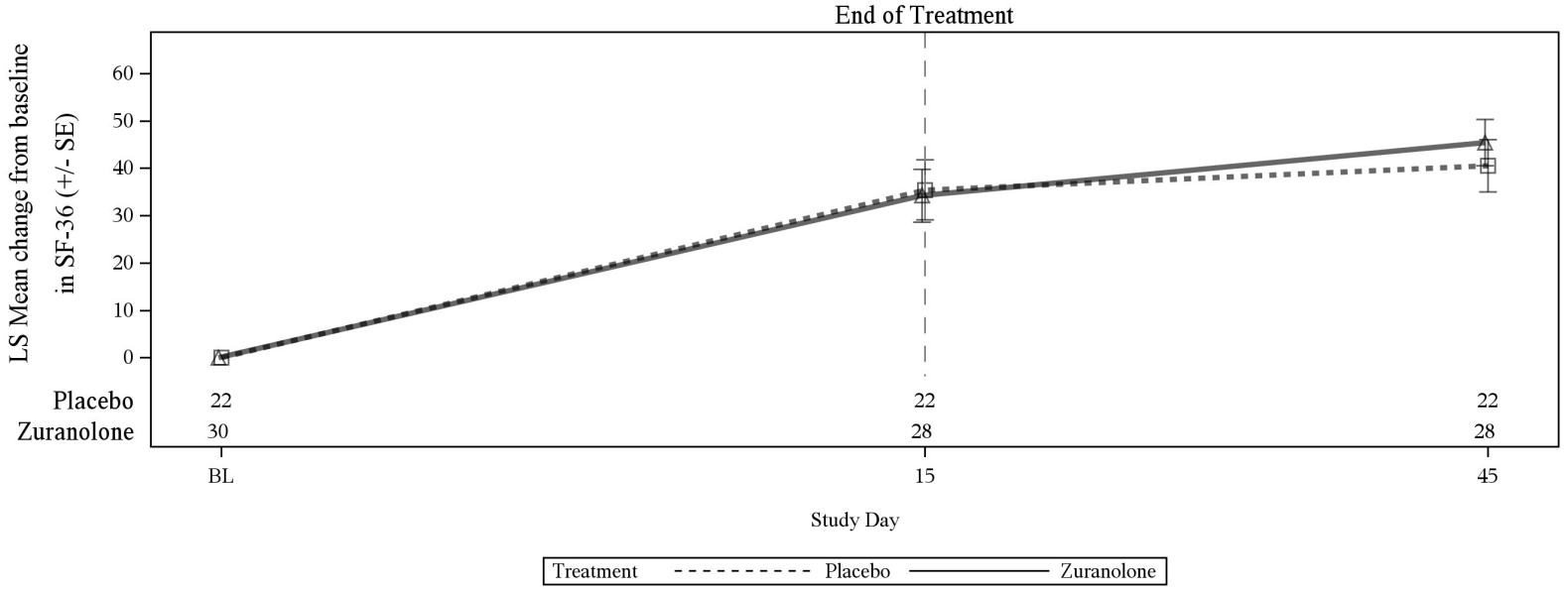
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

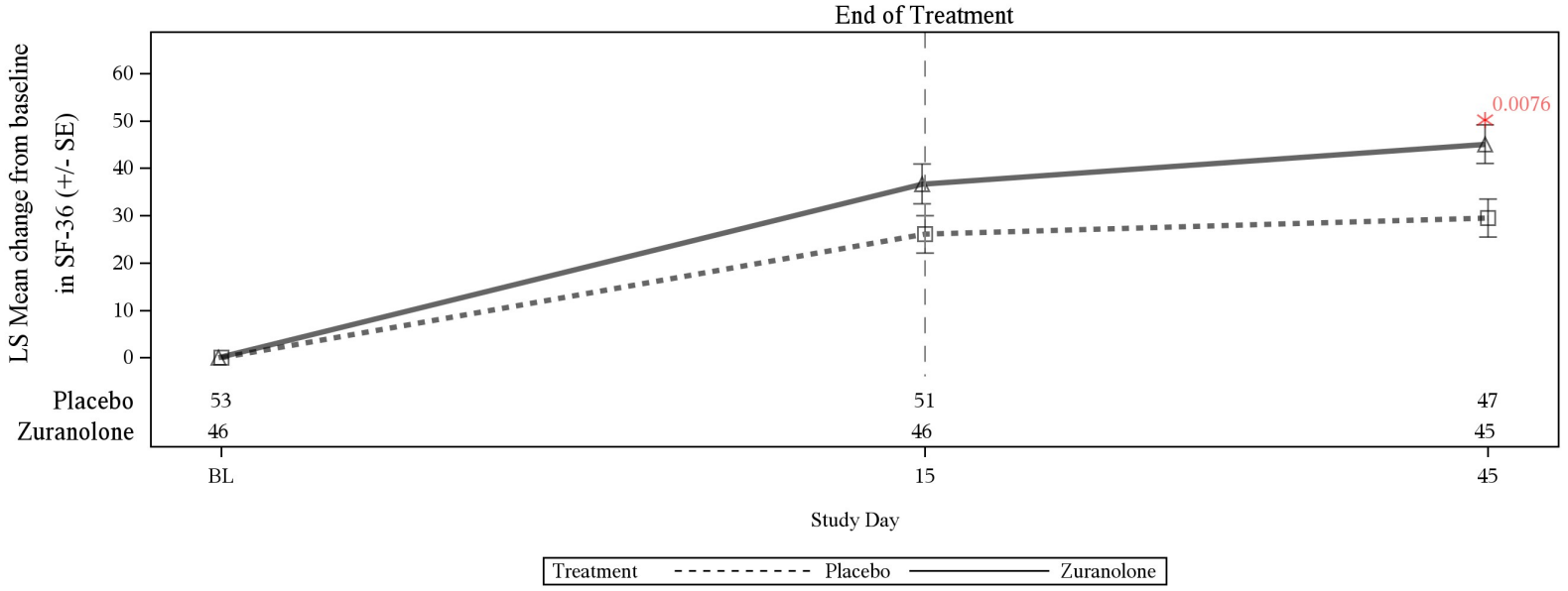
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

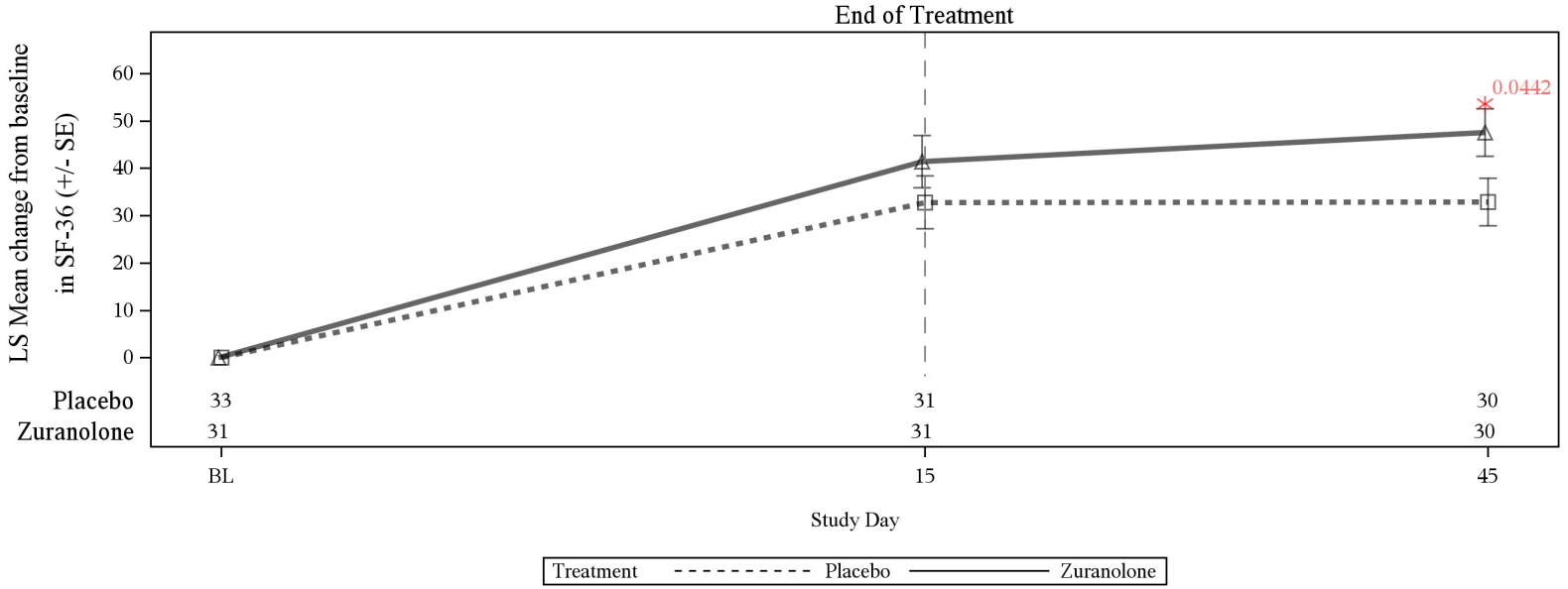
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

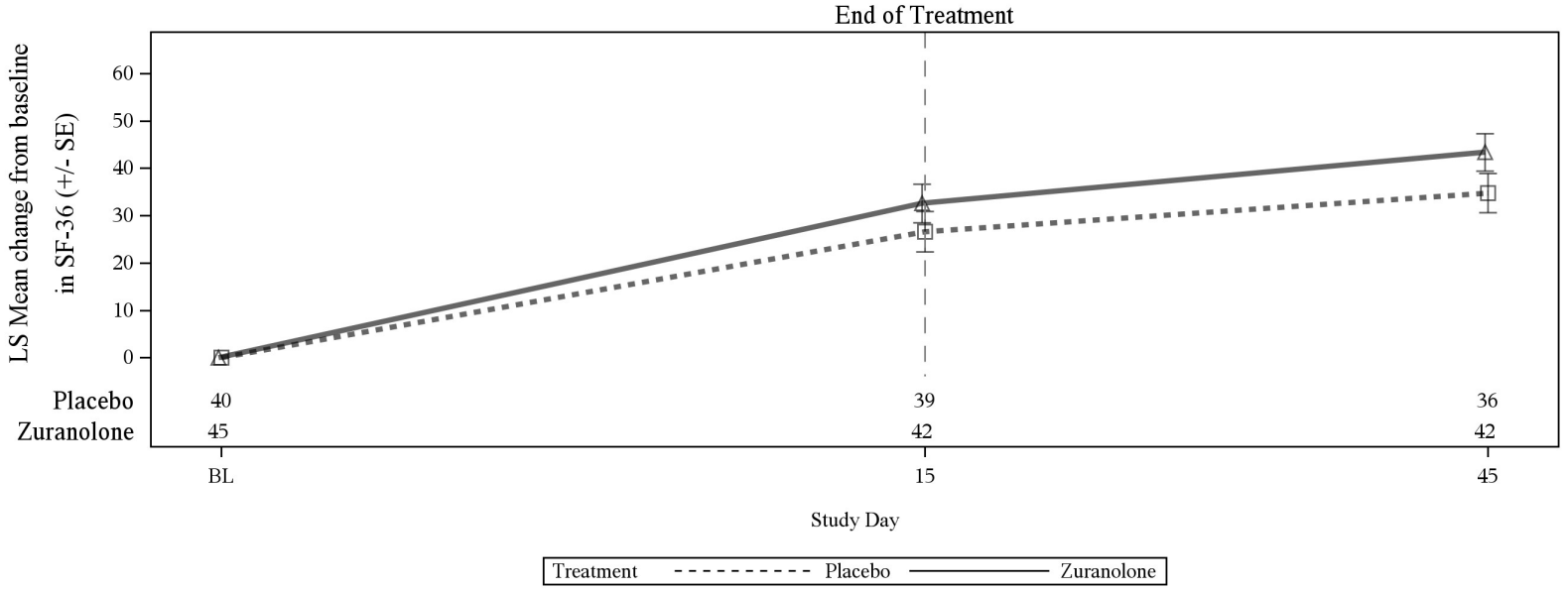
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

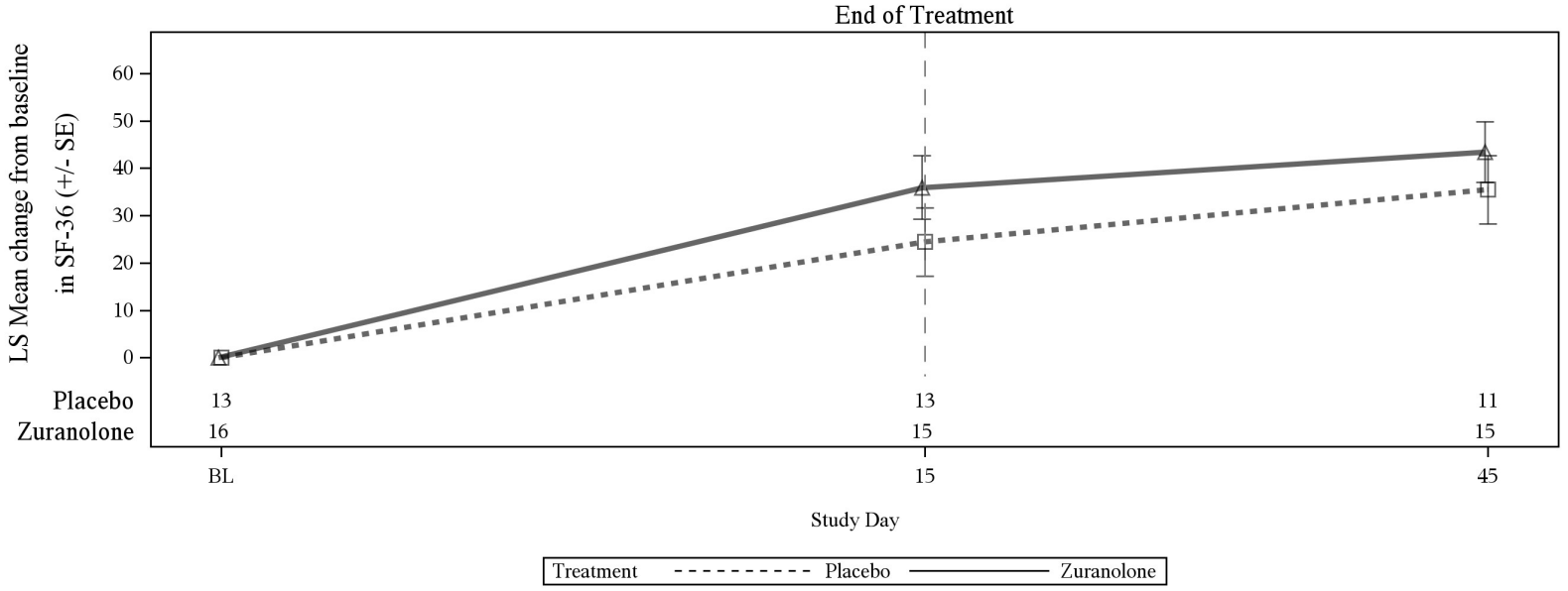
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 7 of 17

Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

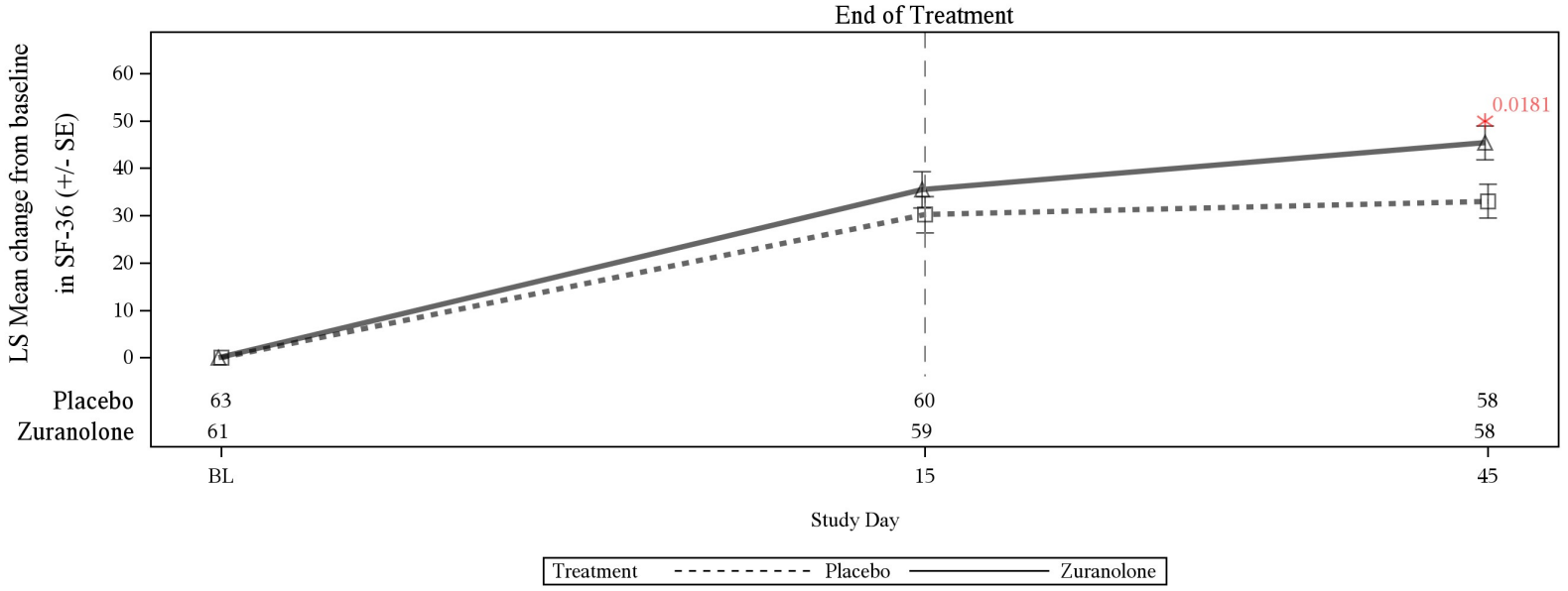
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

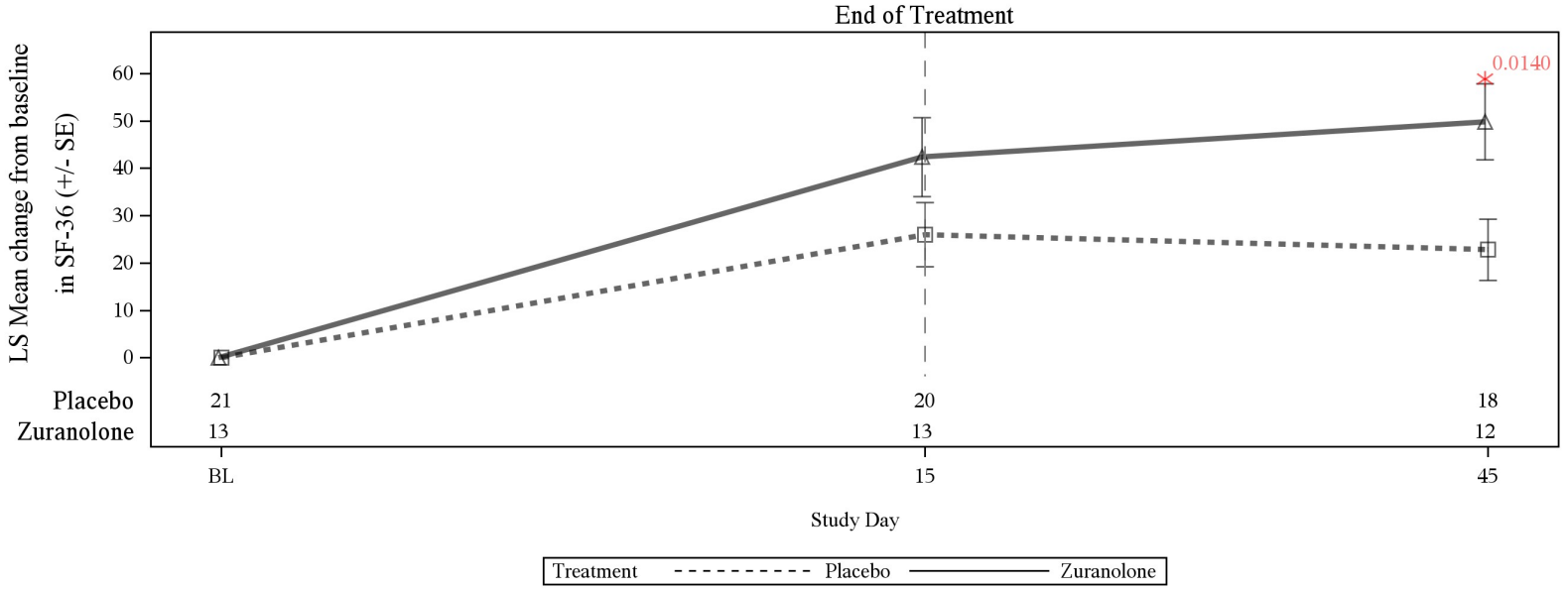
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 9 of 17

BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

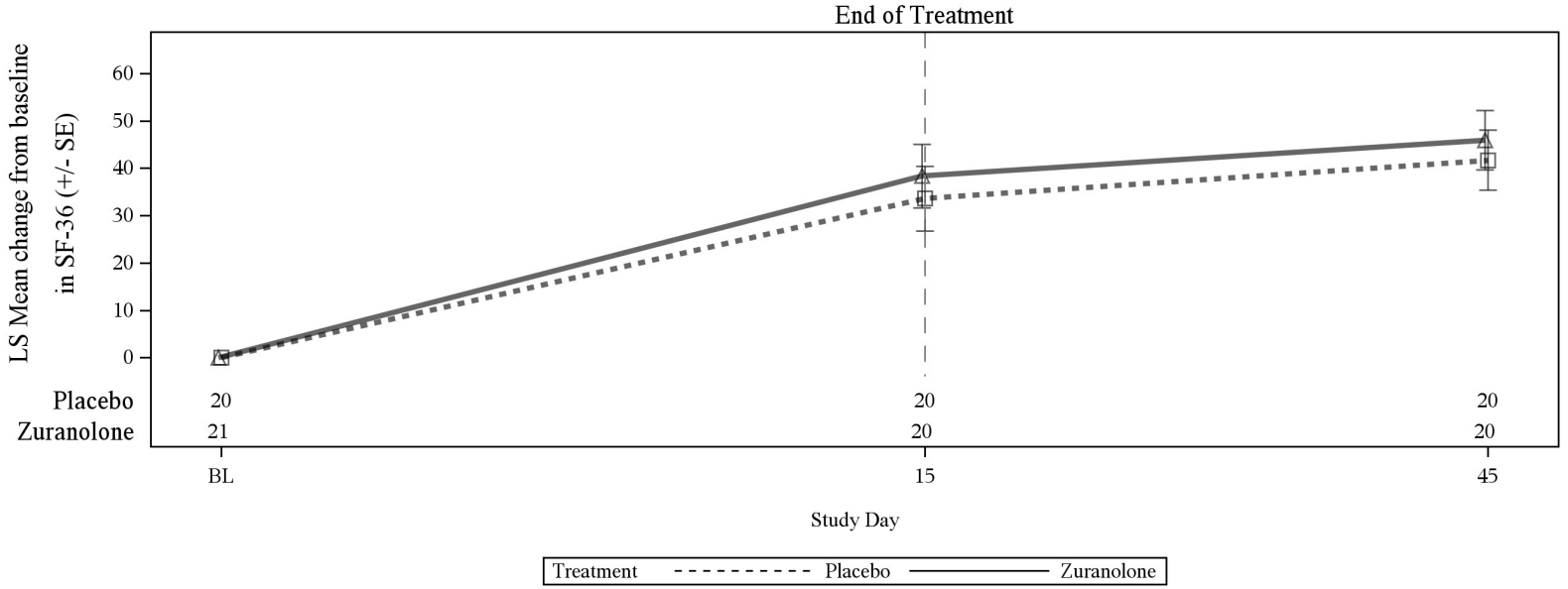
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 10 of 17

BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

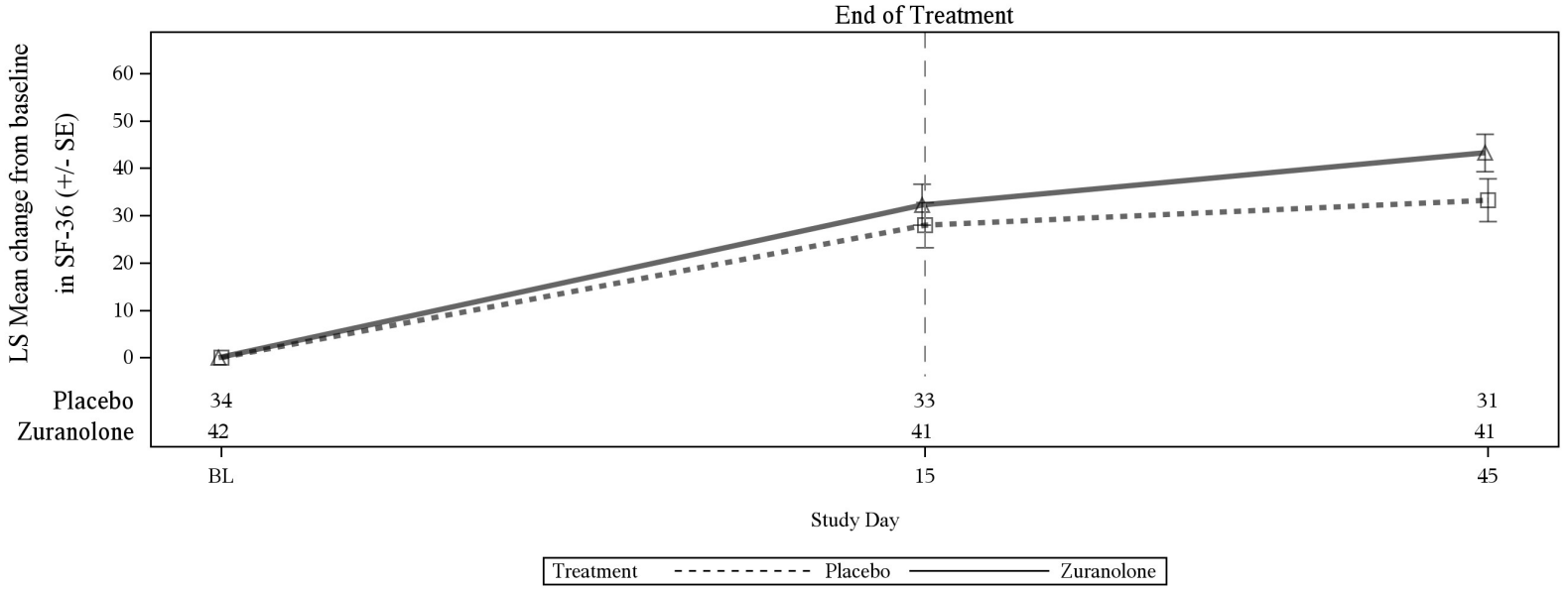
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 11 of 17

BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

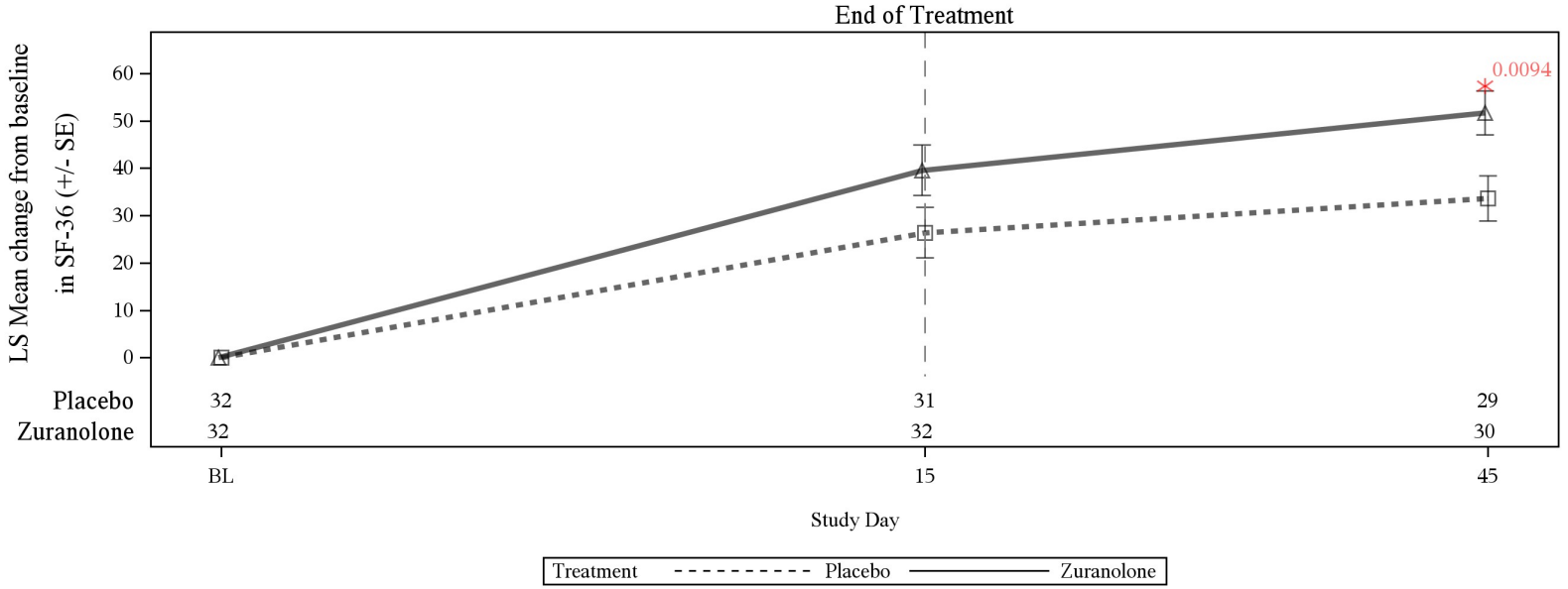
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 12 of 17

Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

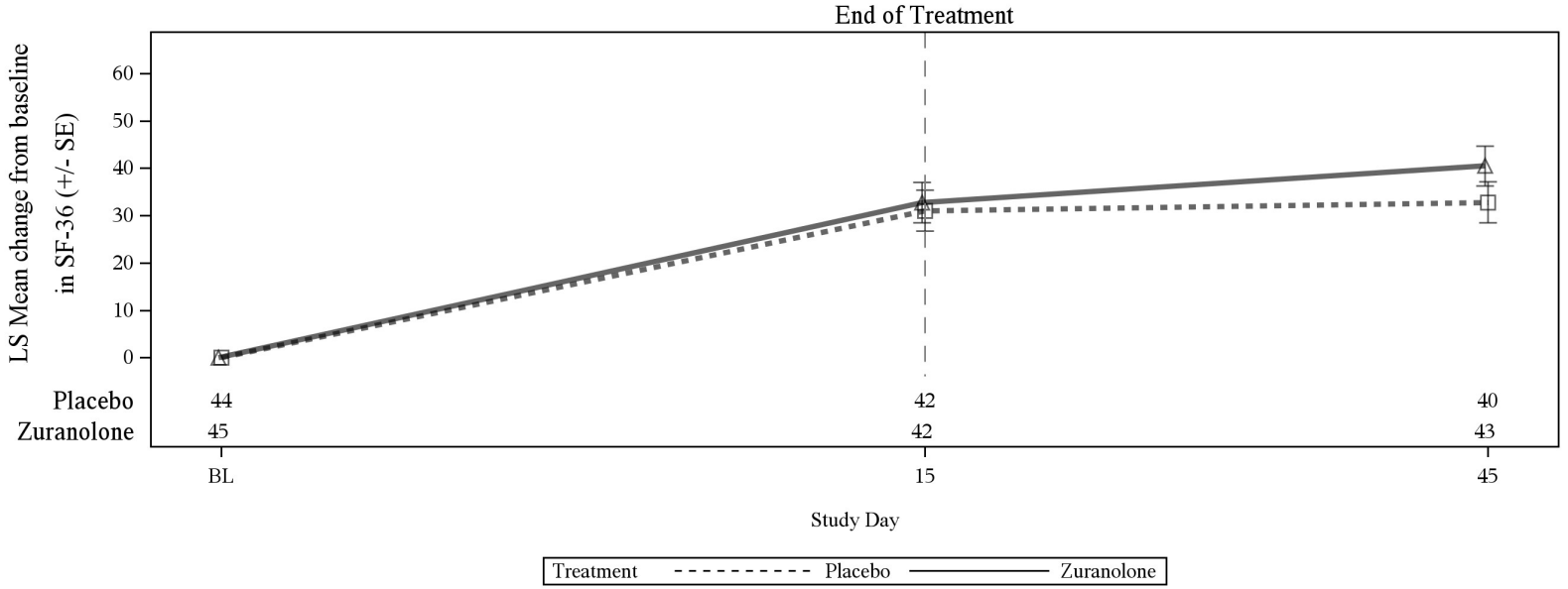
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 13 of 17

Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

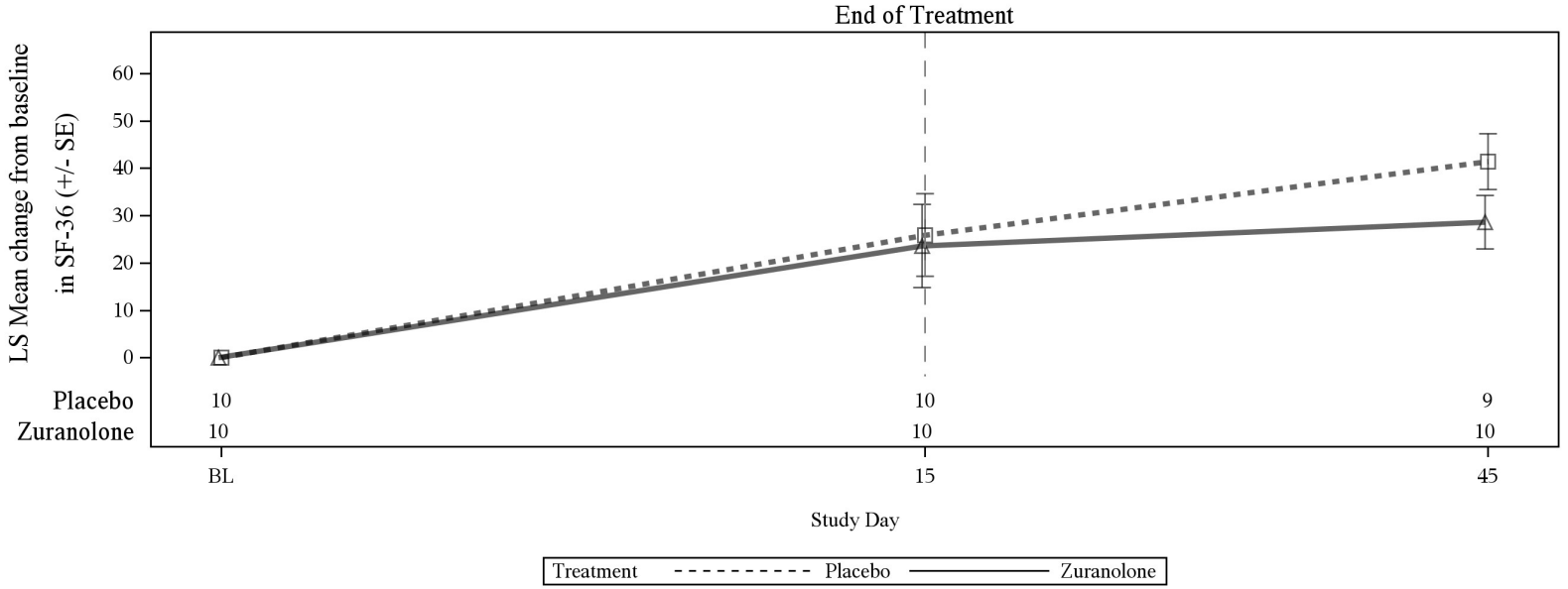
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 14 of 17

Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

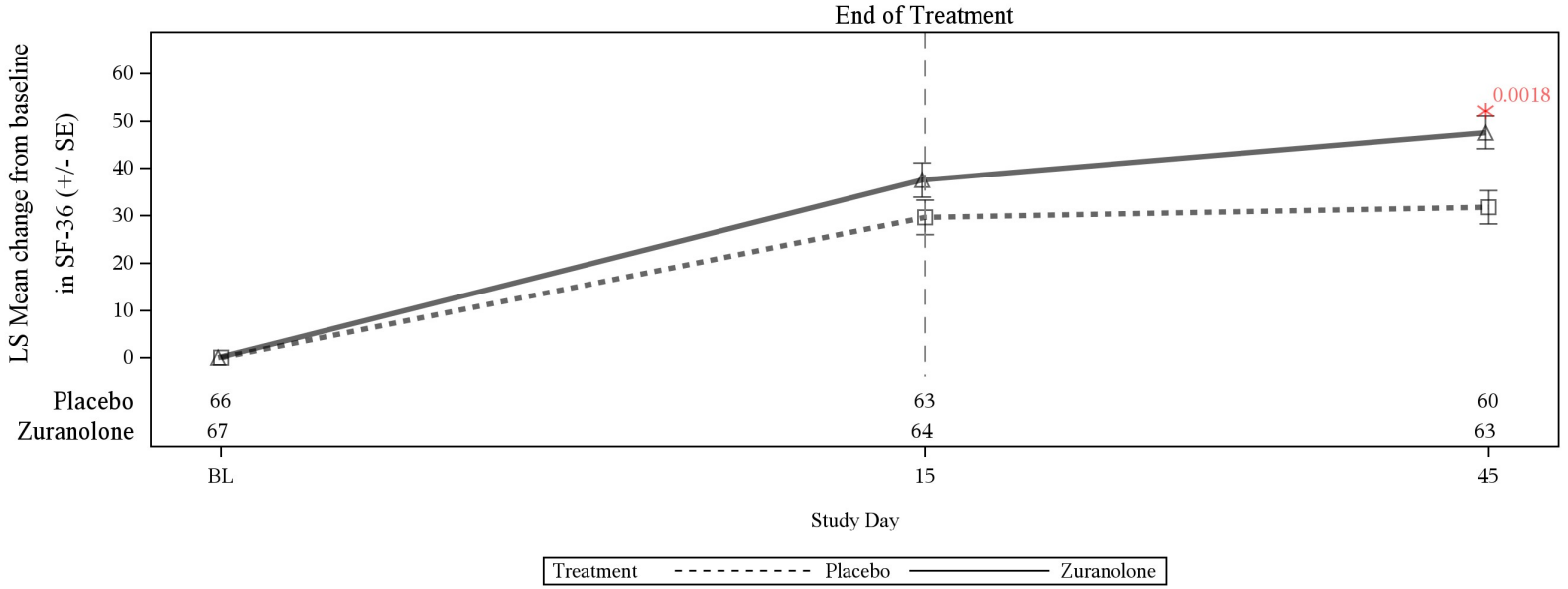
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 15 of 17

Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

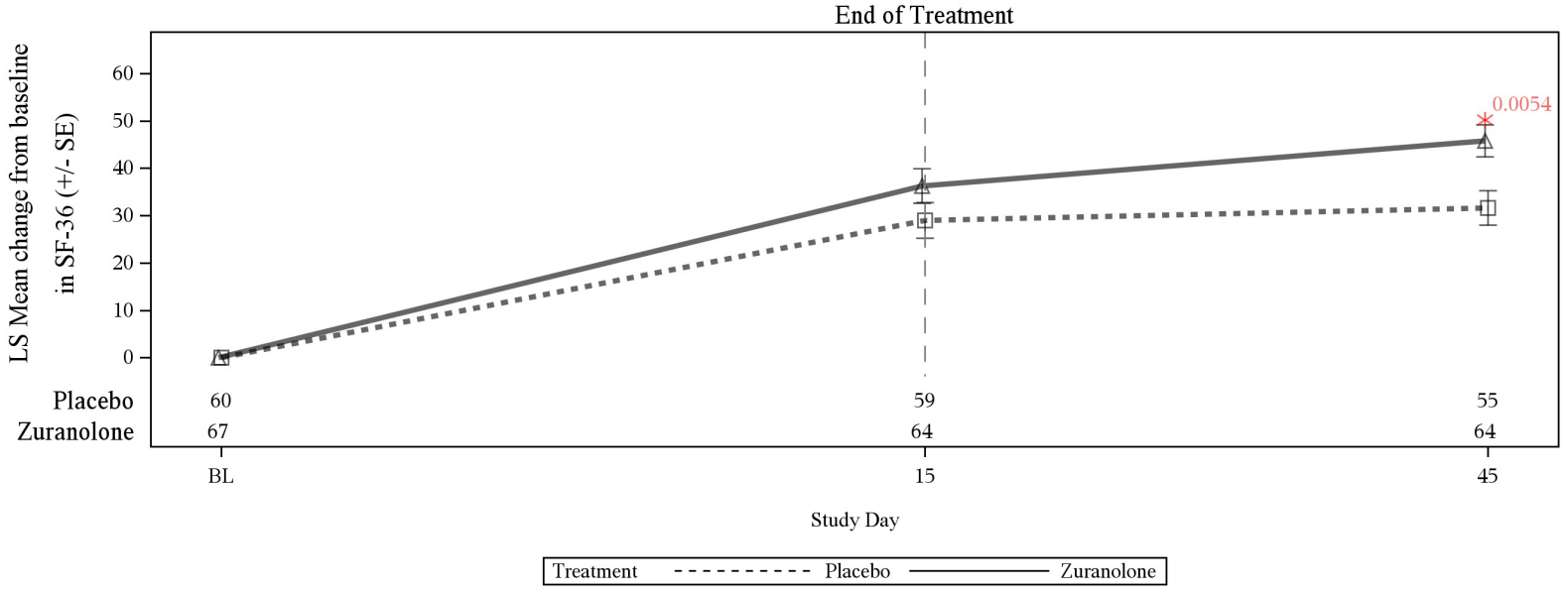
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 16 of 17

History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

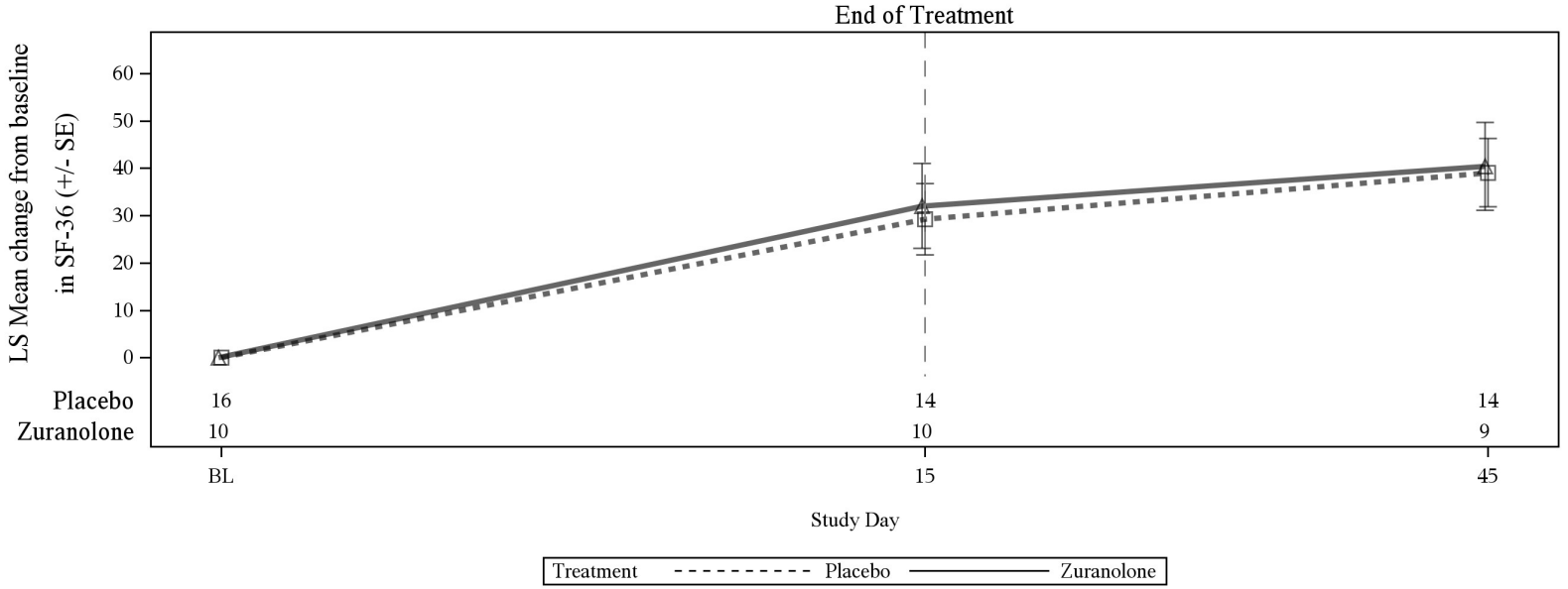
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Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Social Functioning Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 17 of 17

History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-sf-mmrm-201-by.sas:f-sf36-sf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

2.8.2 Ansprechen

2.8.2.1 Responder-Analysen

2.8.2.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with a response, n (%) [2]	43 (57.3)	50 (65.8)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.149
95% CI for the RR		(0.899, 1.470)
p-value for RR		0.2671
OR - Odds Ratio (Zuranolone vs. Placebo)		1.398
95% CI for the OR		(0.716, 2.728)
p-value for OR		0.3266
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.077
95% CI for the ARR		(-0.075, 0.228)
p-value for ARR		0.3202

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score (for the respective parameter) response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	49 (65.3)	62 (81.6)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.218
95% CI for the RR		(1.011, 1.467)
p-value for RR		0.0378
OR - Odds Ratio (Zuranolone vs. Placebo)		2.360
95% CI for the OR		(1.109, 5.023)
p-value for OR		0.0259
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.150
95% CI for the ARR		(0.018, 0.283)
p-value for ARR		0.0261

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score (for the respective parameter) response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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2.8.2.1 .2 Subgruppen

2.8.2.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	43 (57.3)	50 (65.8)	
Number of subjects with response at Day 45, n (%)	49 (65.3)	62 (81.6)	
Age Group (years)			0.1894
Day 15			
18 - 24, n / N (%)	12/25 (48.0)	13/17 (76.5)	
25 - 45, n / N (%)	31/50 (62.0)	37/59 (62.7)	
Day 45			
18 - 24, n / N (%)	14/25 (56.0)	13/17 (76.5)	
25 - 45, n / N (%)	35/50 (70.0)	49/59 (83.1)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.0182
Day 15			
<28, n / N (%)	16/22 (72.7)	18/30 (60.0)	
>=28, n / N (%)	27/53 (50.9)	32/46 (69.6)	
Day 45			
<28, n / N (%)	17/22 (77.3)	25/30 (83.3)	
>=28, n / N (%)	32/53 (60.4)	37/46 (80.4)	
Race Group (Black or African American, White)			0.4365
Day 15			
Black or African American, n / N (%)	18/32 (56.3)	22/31 (71.0)	
White, n / N (%)	23/40 (57.5)	28/44 (63.6)	
Day 45			
Black or African American, n / N (%)	20/32 (62.5)	26/31 (83.9)	
White, n / N (%)	27/40 (67.5)	35/44 (79.5)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.8798
Day 15			
Yes, n / N (%)	7/13 (53.8)	9/16 (56.3)	
No, n / N (%)	36/62 (58.1)	41/60 (68.3)	
Day 45			
Yes, n / N (%)	9/13 (69.2)	12/16 (75.0)	
No, n / N (%)	40/62 (64.5)	50/60 (83.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.0993(a) 0.7657(b) 0.0643(c)
Day 15			
<=24.9, n / N (%)	11/21 (52.4)	9/13 (69.2)	
25-29.9, n / N (%)	13/20 (65.0)	12/21 (57.1)	
>=30, n / N (%)	19/34 (55.9)	29/42 (69.0)	
Day 45			
<=24.9, n / N (%)	11/21 (52.4)	10/13 (76.9)	
25-29.9, n / N (%)	17/20 (85.0)	15/21 (71.4)	
>=30, n / N (%)	21/34 (61.8)	37/42 (88.1)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.6775
Day 15			
3rd Trimester, n / N (%)	17/32 (53.1)	21/32 (65.6)	
Postpartum, n / N (%)	26/43 (60.5)	29/44 (65.9)	
Day 45			
3rd Trimester, n / N (%)	21/32 (65.6)	27/32 (84.4)	
Postpartum, n / N (%)	28/43 (65.1)	35/44 (79.5)	
Family History of PPD			0.5700
Day 15			
Yes, n / N (%)	6/10 (60.0)	6/10 (60.0)	
No/Unknown, n / N (%)	37/65 (56.9)	44/66 (66.7)	
Day 45			
Yes, n / N (%)	8/10 (80.0)	8/10 (80.0)	
No/Unknown, n / N (%)	41/65 (63.1)	54/66 (81.8)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.5607
Day 15			
1st Episode, n / N (%)	34/59 (57.6)	45/66 (68.2)	
Recurrent Episode, n / N (%)	9/16 (56.3)	5/10 (50.0)	
Day 45			
1st Episode, n / N (%)	37/59 (62.7)	55/66 (83.3)	
Recurrent Episode, n / N (%)	12/16 (75.0)	7/10 (70.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	6/8 (75.0)	6/10 (60.0)	
>=20, n / N (%)	37/67 (55.2)	44/66 (66.7)	
Day 45			
<20, n / N (%)	7/8 (87.5)	7/10 (70.0)	
>=20, n / N (%)	42/67 (62.7)	55/66 (83.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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2.8.2.1 .2 .2 Subgruppenanalysen

2.8.2.1 .2 .2 .1 Alter

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 15		
Number of subjects with a response, n (%) [2]	12 (48.0)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.560
95% CI for the RR		(0.956, 2.545)
p-value for RR		0.0753
Day 45		
Number of subjects with a response, n (%) [2]	14 (56.0)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.337
95% CI for the RR		(0.871, 2.053)
p-value for RR		0.1845

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 15		
Number of subjects with a response, n (%) [2]	31 (62.0)	37 (62.7)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.008
95% CI for the RR		(0.757, 1.342)
p-value for RR		0.9583
Day 45		
Number of subjects with a response, n (%) [2]	35 (70.0)	49 (83.1)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.182
95% CI for the RR		(0.956, 1.461)
p-value for RR		0.1218

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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2.8.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 15		
Number of subjects with a response, n (%) [2]	16 (72.7)	18 (60.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.817
95% CI for the RR		(0.555, 1.203)
p-value for RR		0.3049
Day 45		
Number of subjects with a response, n (%) [2]	17 (77.3)	25 (83.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.067
95% CI for the RR		(0.813, 1.402)
p-value for RR		0.6391

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 15		
Number of subjects with a response, n (%) [2]	27 (50.9)	32 (69.6)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.382
95% CI for the RR		(1.009, 1.893)
p-value for RR		0.0440
Day 45		
Number of subjects with a response, n (%) [2]	32 (60.4)	37 (80.4)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.348
95% CI for the RR		(1.045, 1.739)
p-value for RR		0.0216

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.8.2.1 .2 .2 .3 Abstammung

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 15		
Number of subjects with a response, n (%) [2]	18 (56.3)	22 (71.0)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.134
95% CI for the RR		(0.803, 1.603)
p-value for RR		0.4750
Day 45		
Number of subjects with a response, n (%) [2]	20 (62.5)	26 (83.9)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.249
95% CI for the RR		(0.938, 1.662)
p-value for RR		0.1281

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 15		
Number of subjects with a response, n (%) [2]	23 (57.5)	28 (63.6)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.141
95% CI for the RR		(0.808, 1.611)
p-value for RR		0.4549
Day 45		
Number of subjects with a response, n (%) [2]	27 (67.5)	35 (79.5)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.171
95% CI for the RR		(0.902, 1.521)
p-value for RR		0.2357

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.8.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 15		
Number of subjects with a response, n (%) [2]	7 (53.8)	9 (56.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.313
95% CI for the RR		(0.649, 2.657)
p-value for RR		0.4485
Day 45		
Number of subjects with a response, n (%) [2]	9 (69.2)	12 (75.0)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.112
95% CI for the RR		(0.720, 1.717)
p-value for RR		0.6334

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 15		
Number of subjects with a response, n (%) [2]	36 (58.1)	41 (68.3)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.137
95% CI for the RR		(0.875, 1.478)
p-value for RR		0.3355
Day 45		
Number of subjects with a response, n (%) [2]	40 (64.5)	50 (83.3)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.245
95% CI for the RR		(1.008, 1.537)
p-value for RR		0.0415

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.8.2.1 .2 .2 .5 BMI

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 15		
Number of subjects with a response, n (%) [2]	11 (52.4)	9 (69.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.325
95% CI for the RR		(0.778, 2.260)
p-value for RR		0.3005
Day 45		
Number of subjects with a response, n (%) [2]	11 (52.4)	10 (76.9)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.473
95% CI for the RR		(0.902, 2.404)
p-value for RR		0.1215

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 15		
Number of subjects with a response, n (%) [2]	13 (65.0)	12 (57.1)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.896
95% CI for the RR		(0.560, 1.436)
p-value for RR		0.6489
Day 45		
Number of subjects with a response, n (%) [2]	17 (85.0)	15 (71.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.857
95% CI for the RR		(0.636, 1.154)
p-value for RR		0.3095

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 15		
Number of subjects with a response, n (%) [2]	19 (55.9)	29 (69.0)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.210
95% CI for the RR		(0.849, 1.725)
p-value for RR		0.2914
Day 45		
Number of subjects with a response, n (%) [2]	21 (61.8)	37 (88.1)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.397
95% CI for the RR		(1.057, 1.847)
p-value for RR		0.0189

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.8.2.1 .2 .2 .6 Beginn der PPD

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 15		
Number of subjects with a response, n (%) [2]	17 (53.1)	21 (65.6)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.221
95% CI for the RR		(0.814, 1.830)
p-value for RR		0.3342
Day 45		
Number of subjects with a response, n (%) [2]	21 (65.6)	27 (84.4)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.271
95% CI for the RR		(0.957, 1.687)
p-value for RR		0.0974

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 15		
Number of subjects with a response, n (%) [2]	26 (60.5)	29 (65.9)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.091
95% CI for the RR		(0.798, 1.490)
p-value for RR		0.5860
Day 45		
Number of subjects with a response, n (%) [2]	28 (65.1)	35 (79.5)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.222
95% CI for the RR		(0.942, 1.586)
p-value for RR		0.1310

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.8.2.1 .2 .2 .7 PPD in der Familie

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 15		
Number of subjects with a response, n (%) [2]	6 (60.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.181
95% CI for the RR		(0.644, 2.167)
p-value for RR		0.5910
Day 45		
Number of subjects with a response, n (%) [2]	8 (80.0)	8 (80.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.181
95% CI for the RR		(0.818, 1.705)
p-value for RR		0.3739

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 15		
Number of subjects with a response, n (%) [2]	37 (56.9)	44 (66.7)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.147
95% CI for the RR		(0.876, 1.501)
p-value for RR		0.3186
Day 45		
Number of subjects with a response, n (%) [2]	41 (63.1)	54 (81.8)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.270
95% CI for the RR		(1.027, 1.571)
p-value for RR		0.0273

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.8.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 15		
Number of subjects with a response, n (%) [2]	34 (57.6)	45 (68.2)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.146
95% CI for the RR		(0.873, 1.505)
p-value for RR		0.3269
Day 45		
Number of subjects with a response, n (%) [2]	37 (62.7)	55 (83.3)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.287
95% CI for the RR		(1.031, 1.607)
p-value for RR		0.0257

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 15		
Number of subjects with a response, n (%) [2]	9 (56.3)	5 (50.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.031
95% CI for the RR		(0.449, 2.367)
p-value for RR		0.9427
Day 45		
Number of subjects with a response, n (%) [2]	12 (75.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.082
95% CI for the RR		(0.566, 2.071)
p-value for RR		0.8107

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Social Functioning subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

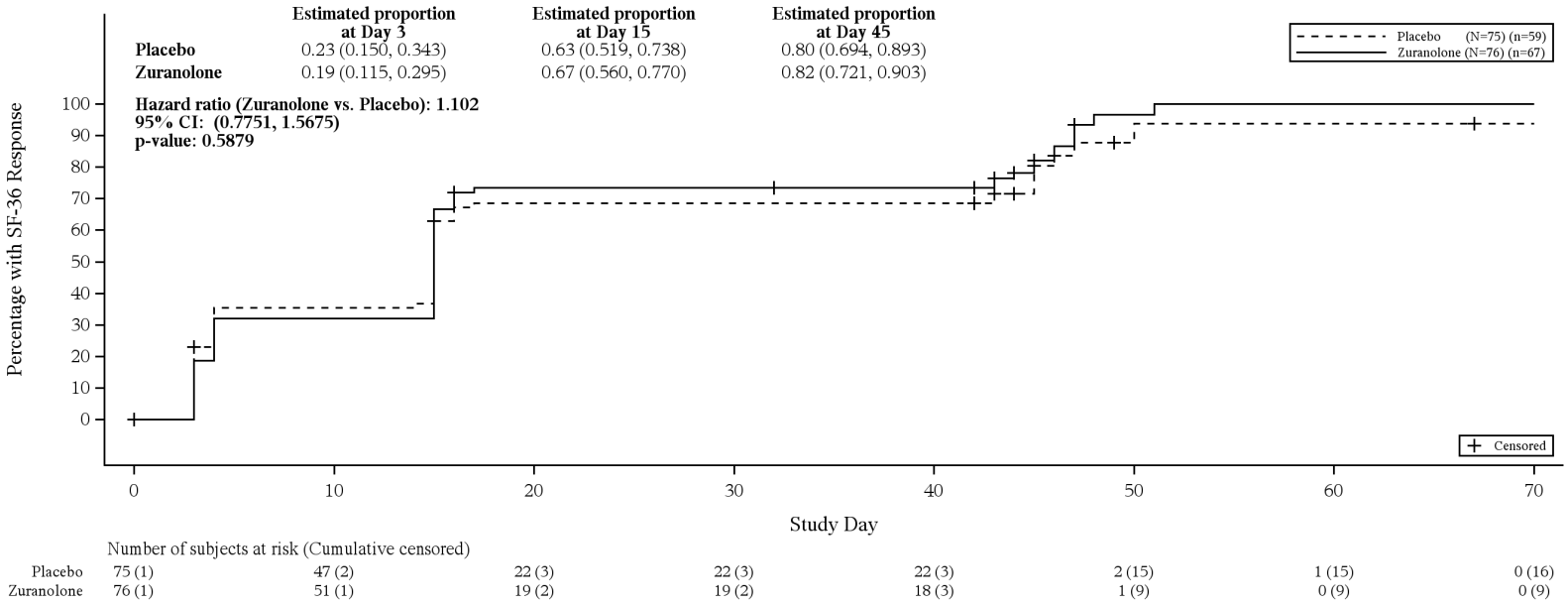
Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-201-by.sas:t-sf36-sf-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.8.2.2 TTE-Analysen

2.8.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-ovr.sas:f-sf36-sf-resp15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	59 (78.7)	67 (88.2)
Time to first SF-36 Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 4.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	45.0 (16.0 , 47.0)	43.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.102
95% CI for the HR		(0.7751 , 1.5675)
p-value for the HR		0.5879

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-ovr.sas:t-sf36-sf-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.8.2.2 .2 Subgruppen

2.8.2.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	59 (78.7)	67 (88.2)	
Age Group (years)			
18 - 24, n / N (%)	18/25 (72.0)	16/17 (94.1)	0.2357
25 - 45, n / N (%)	41/50 (82.0)	51/59 (86.4)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	21/22 (95.5)	26/30 (86.7)	0.1611
>=28, n / N (%)	38/53 (71.7)	41/46 (89.1)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	25/32 (78.1)	29/31 (93.5)	0.4115
White, n / N (%)	32/40 (80.0)	37/44 (84.1)	
Antidepressant Use at Baseline			
Yes, n / N (%)	12/13 (92.3)	12/16 (75.0)	0.5789
No, n / N (%)	47/62 (75.8)	55/60 (91.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-int.sas:t-sf36-sf-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	14/21 (66.7)	12/13 (92.3)	0.1564(a)
25-29.9, n / N (%)	18/20 (90.0)	16/21 (76.2)	0.1381(b)
>=30, n / N (%)	27/34 (79.4)	39/42 (92.9)	0.9306(c)
Onset of PPD			
3rd Trimester, n / N (%)	26/32 (81.3)	30/32 (93.8)	0.8168
Postpartum, n / N (%)	33/43 (76.7)	37/44 (84.1)	
Family History of PPD			
Yes, n / N (%)	10/10 (100.0)	8/10 (80.0)	0.3876
No/Unknown, n / N (%)	49/65 (75.4)	59/66 (89.4)	
History of PPD			
1st Episode, n / N (%)	46/59 (78.0)	59/66 (89.4)	0.6635
Recurrent Episode, n / N (%)	13/16 (81.3)	8/10 (80.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	7/8 (87.5)	8/10 (80.0)	NA
>=20, n / N (%)	52/67 (77.6)	59/66 (89.4)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-int.sas:t-sf36-sf-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.8.2.2 .2 .2 Subgruppenanalysen

2.8.2.2 .2 .2 .1 Alter

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	18 (72.0)	16 (94.1)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 45.0)	15.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	15.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.577
95% CI for the HR		(0.7802 , 3.1886)
p-value for the HR		0.2045

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	41 (82.0)	51 (86.4)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (14.0 , 15.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	43.0 (15.0 , 47.0)	44.0 (15.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.978
95% CI for the HR		(0.6457 , 1.4814)
p-value for the HR		0.9165

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.8.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	21 (95.5)	26 (86.7)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	15.0 (15.0 , 45.0)	43.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.764
95% CI for the HR		(0.4117 , 1.4194)
p-value for the HR		0.3949

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	38 (71.7)	41 (89.1)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 14.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (14.0 , 43.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	46.0 (17.0, NE)	43.0 (15.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.313
95% CI for the HR		(0.8379 , 2.0579)
p-value for the HR		0.2347

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.8.2.2 .2 .2 .3 Abstammung

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	25 (78.1)	29 (93.5)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (4.0 , 43.0)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	16.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.253
95% CI for the HR		(0.7262 , 2.1624)
p-value for the HR		0.4176

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	32 (80.0)	37 (84.1)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 16.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	45.0 (15.0 , 48.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.953
95% CI for the HR		(0.5922 , 1.5339)
p-value for the HR		0.8432

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.8.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	12 (92.3)	12 (75.0)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (3.0 , 16.0)	15.0 (15.0 , 46.0)
75th percentile - Q3 (95% CI)	16.0 (15.0, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.839
95% CI for the HR		(0.3527 , 1.9947)
p-value for the HR		0.6907

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	47 (75.8)	55 (91.7)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 14.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (15.0 , 16.0)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (16.0, NE)	16.5 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.154
95% CI for the HR		(0.7793 , 1.7091)
p-value for the HR		0.4743

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.8.2.2 .2 .2 .5 BMI

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	14 (66.7)	12 (92.3)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 45.0)	15.0 (4.0 , 17.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	17.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.756
95% CI for the HR		(0.7758 , 3.9755)
p-value for the HR		0.1767

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	18 (90.0)	16 (76.2)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (3.0 , 43.0)	15.0 (4.0 , 45.0)
75th percentile - Q3 (95% CI)	43.0 (15.0, NE)	45.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.910
95% CI for the HR		(0.4566 , 1.8136)
p-value for the HR		0.7887

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	27 (79.4)	39 (92.9)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 16.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	43.0 (15.0, NE)	16.0 (15.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.879
95% CI for the HR		(0.5297 , 1.4592)
p-value for the HR		0.6184

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.8.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	26 (81.3)	30 (93.8)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (3.0 , 43.0)	9.5 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	15.0 (15.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.164
95% CI for the HR		(0.6770 , 2.0014)
p-value for the HR		0.5828

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	33 (76.7)	37 (84.1)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 16.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	47.0 (15.0, NE)	45.0 (16.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.049
95% CI for the HR		(0.6512 , 1.6902)
p-value for the HR		0.8437

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.8.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	10 (100.0)	8 (80.0)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	9.5 (3.0 , 45.0)	15.0 (3.0, NE)
75th percentile - Q3 (95% CI)	45.0 (4.0, NE)	47.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.835
95% CI for the HR		(0.2795 , 2.4930)
p-value for the HR		0.7464

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	49 (75.4)	59 (89.4)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	17.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.165
95% CI for the HR		(0.7955 , 1.7048)
p-value for the HR		0.4333

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.8.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	46 (78.0)	59 (89.4)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (15.0 , 16.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	45.0 (16.0, NE)	17.0 (15.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.151
95% CI for the HR		(0.7795 , 1.6987)
p-value for the HR		0.4798

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-resp15-tte-201-by.sas:t-sf36-sf-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	13 (81.3)	8 (80.0)
Time to first Social Functioning Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (3.0 , 45.0)	15.0 (3.0, NE)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	48.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.361
95% CI for the HR		(0.4652 , 3.9827)
p-value for the HR		0.5735

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

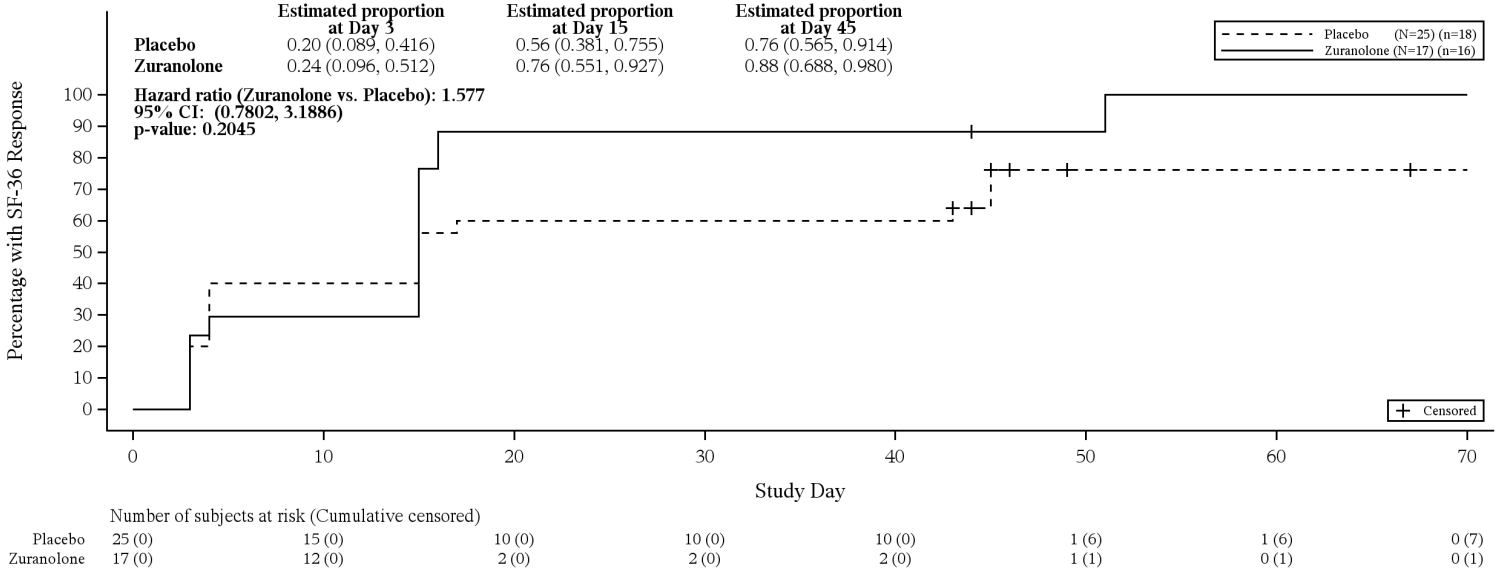
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2.8.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

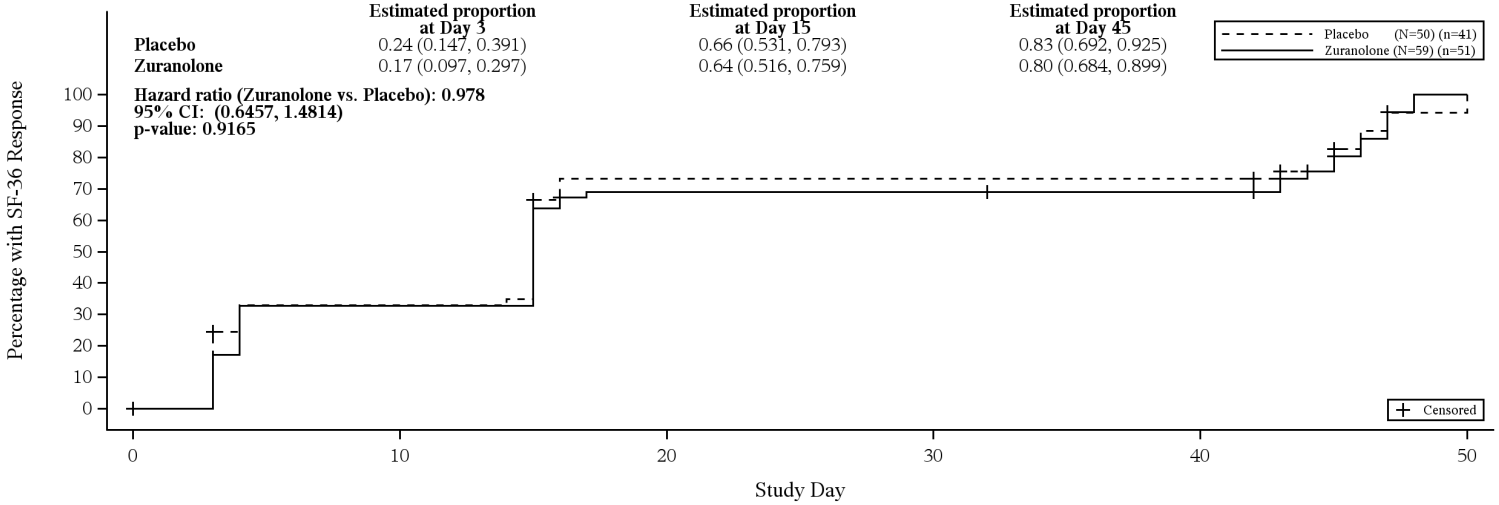
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Number of subjects at risk (Cumulative censored)

Placebo	50 (1)	32 (2)	12 (3)	12 (3)	12 (3)	1 (9)
Zuranolone	59 (1)	39 (1)	17 (2)	17 (2)	16 (3)	0 (8)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

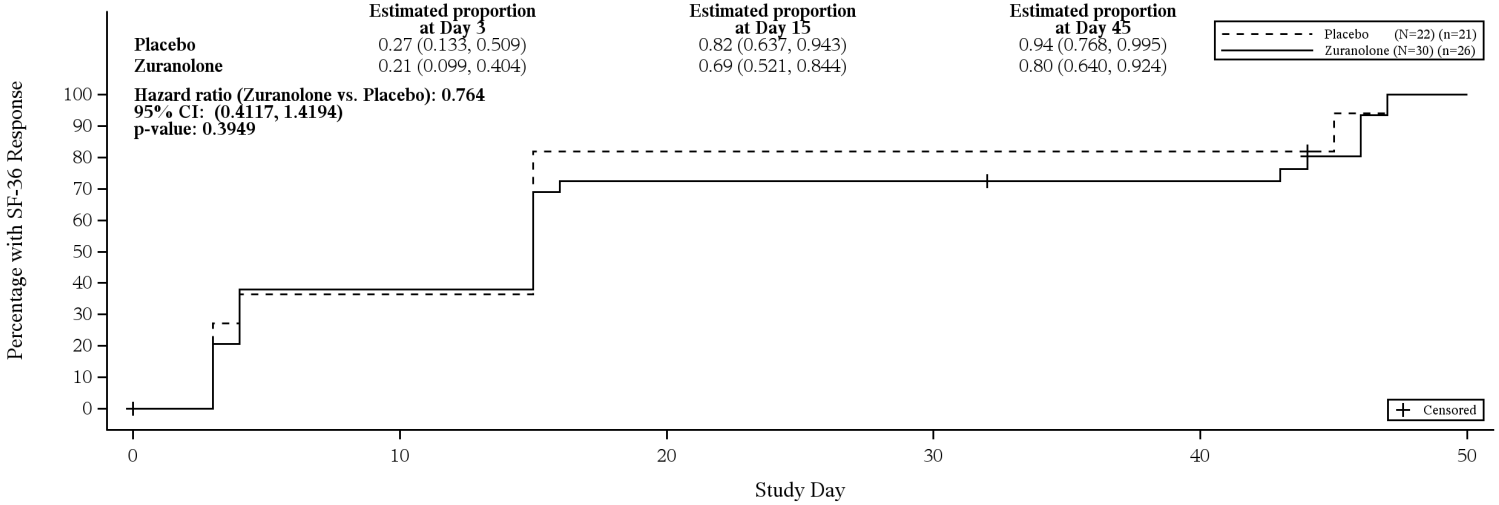
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

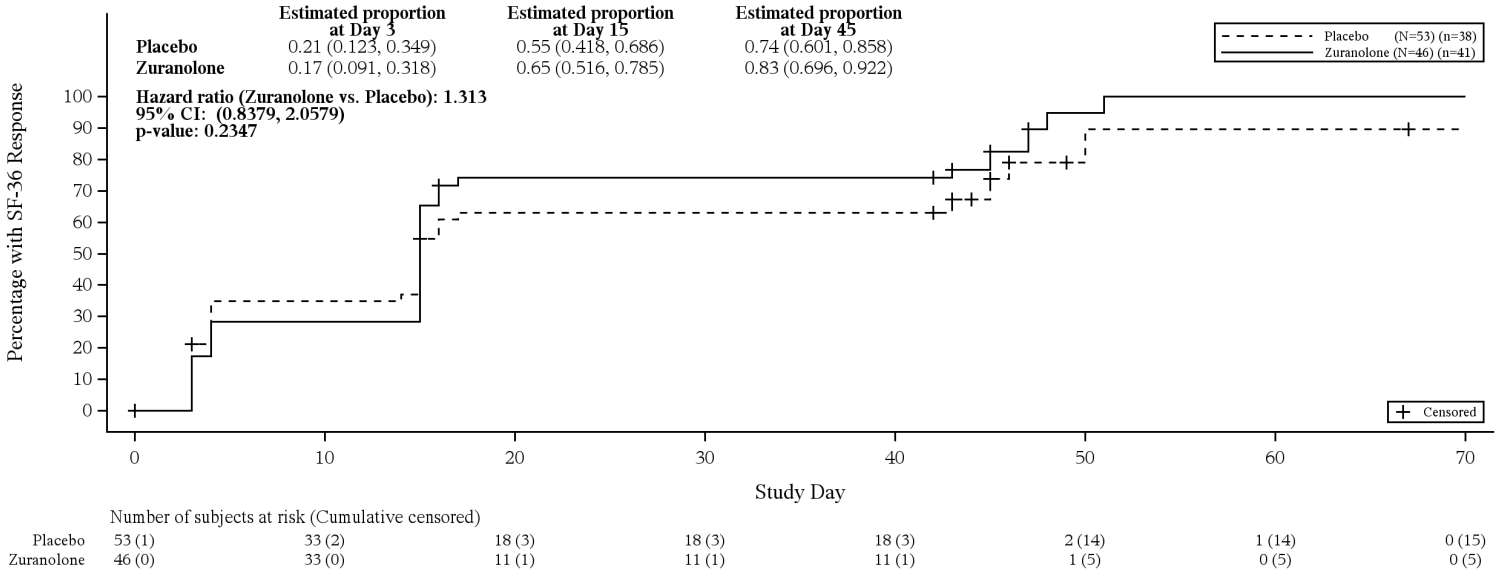
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

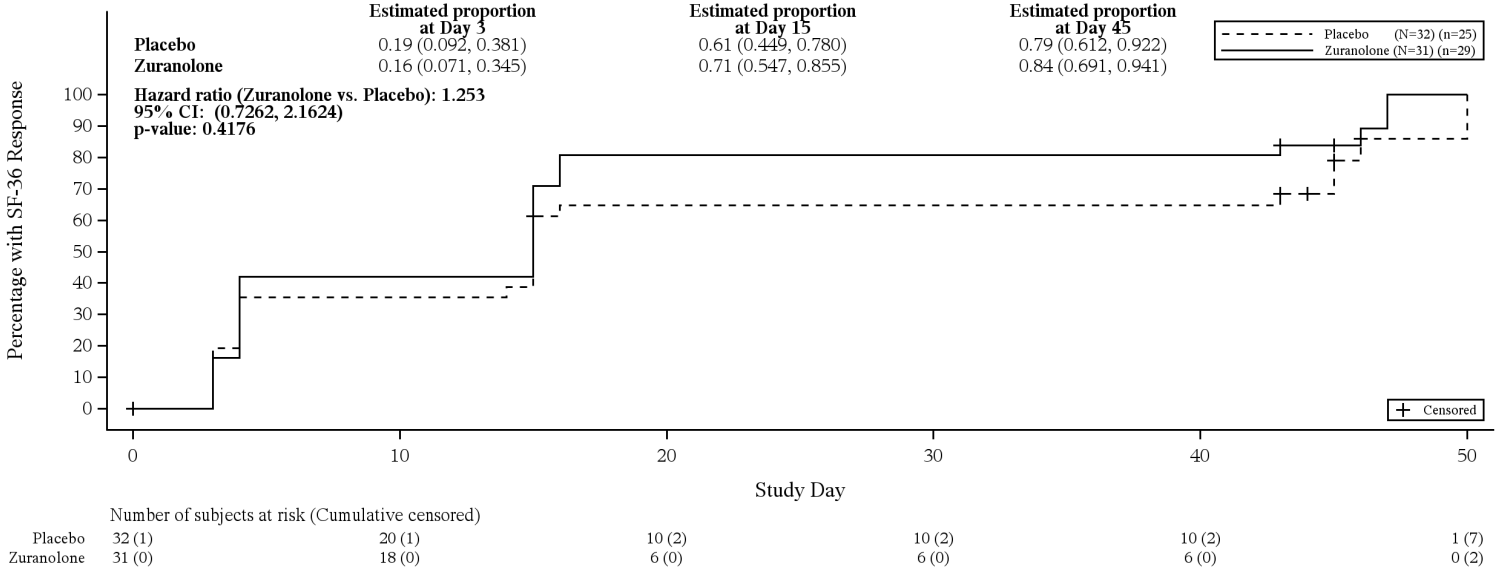
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

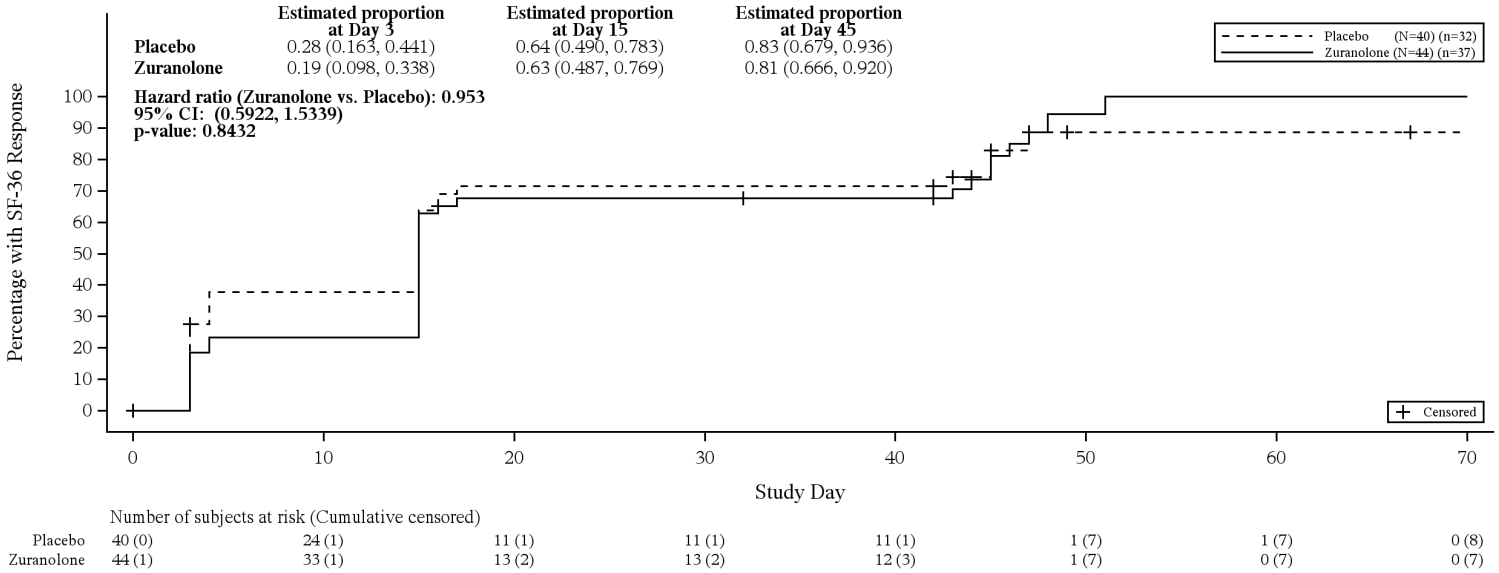
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

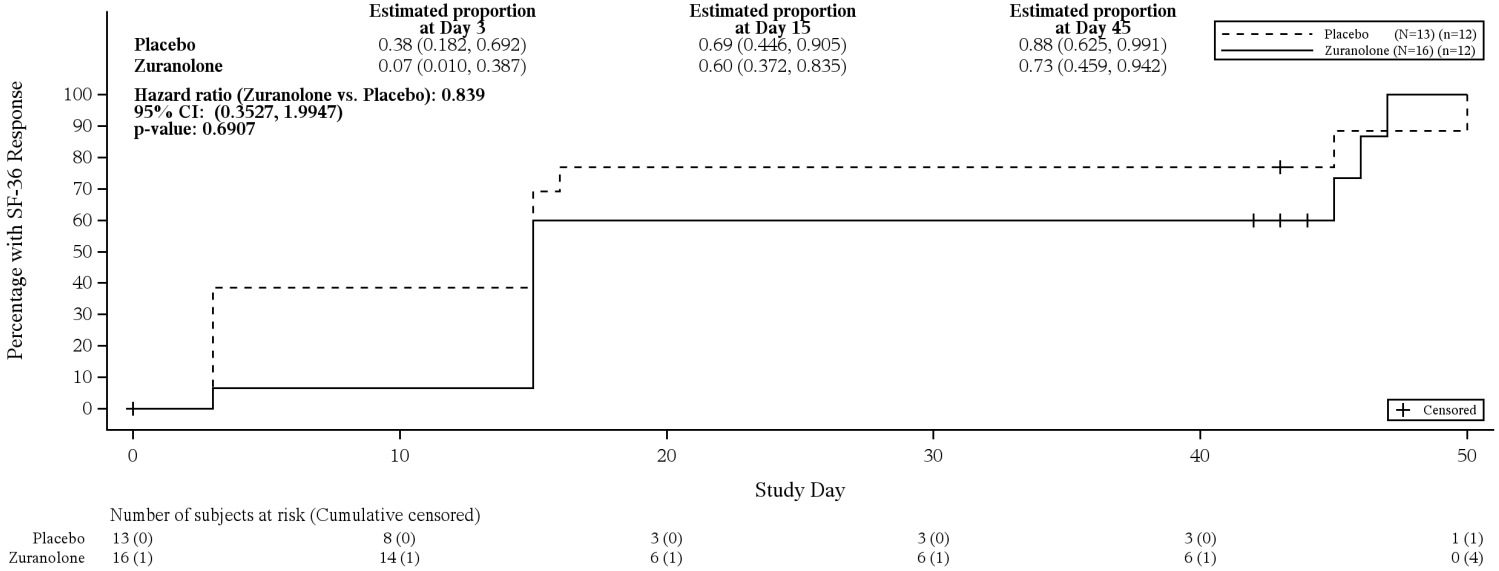
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

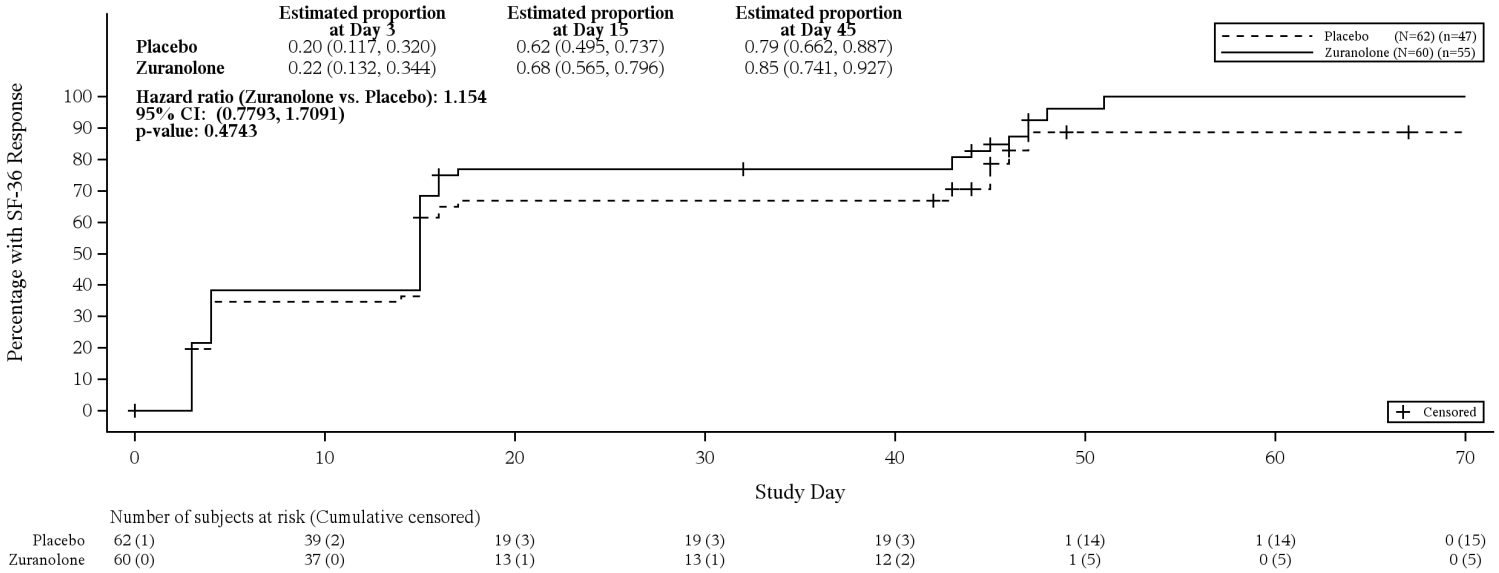
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

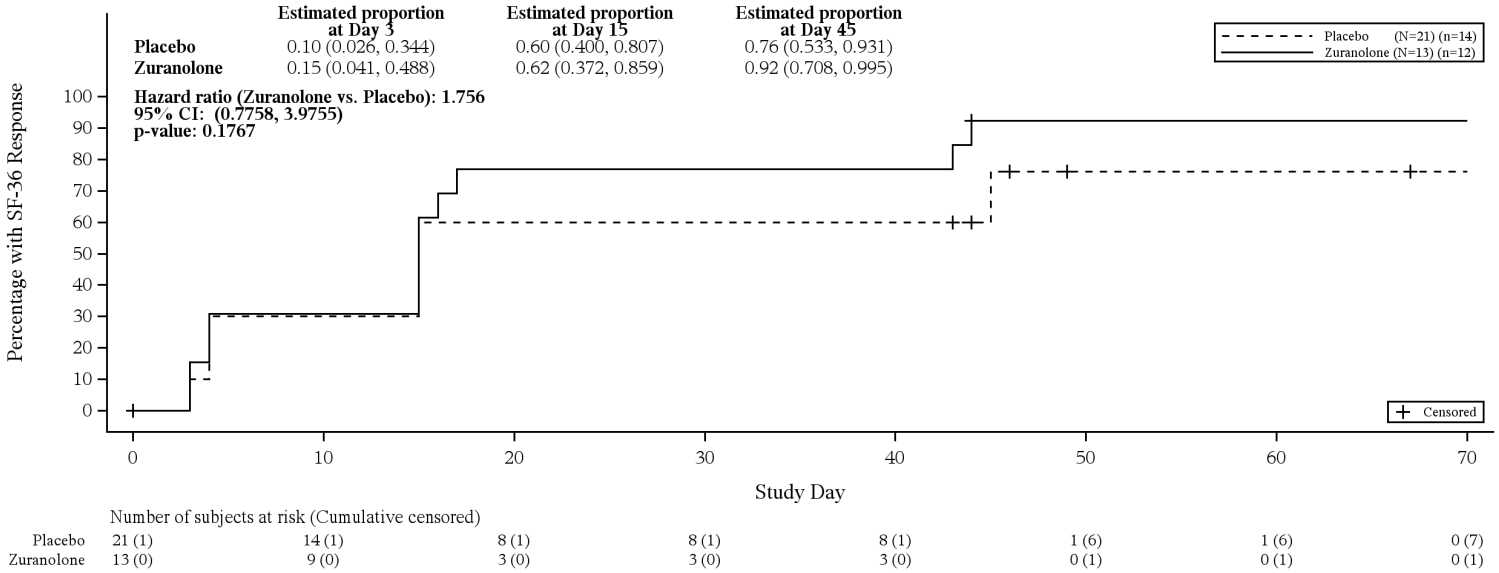
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

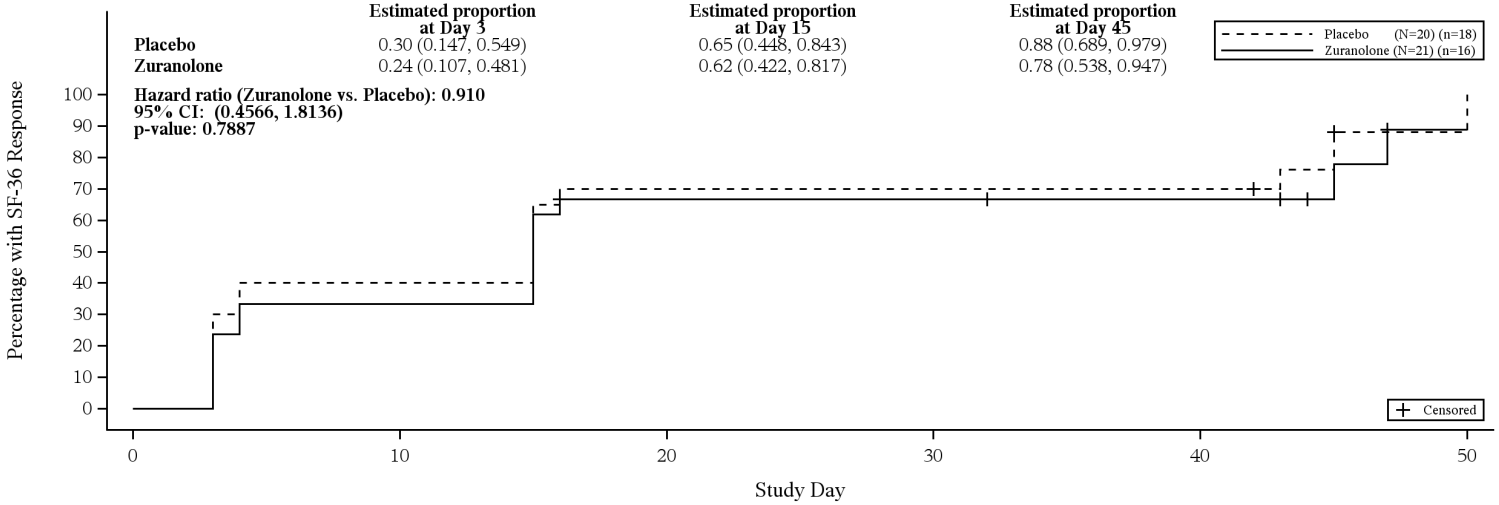
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

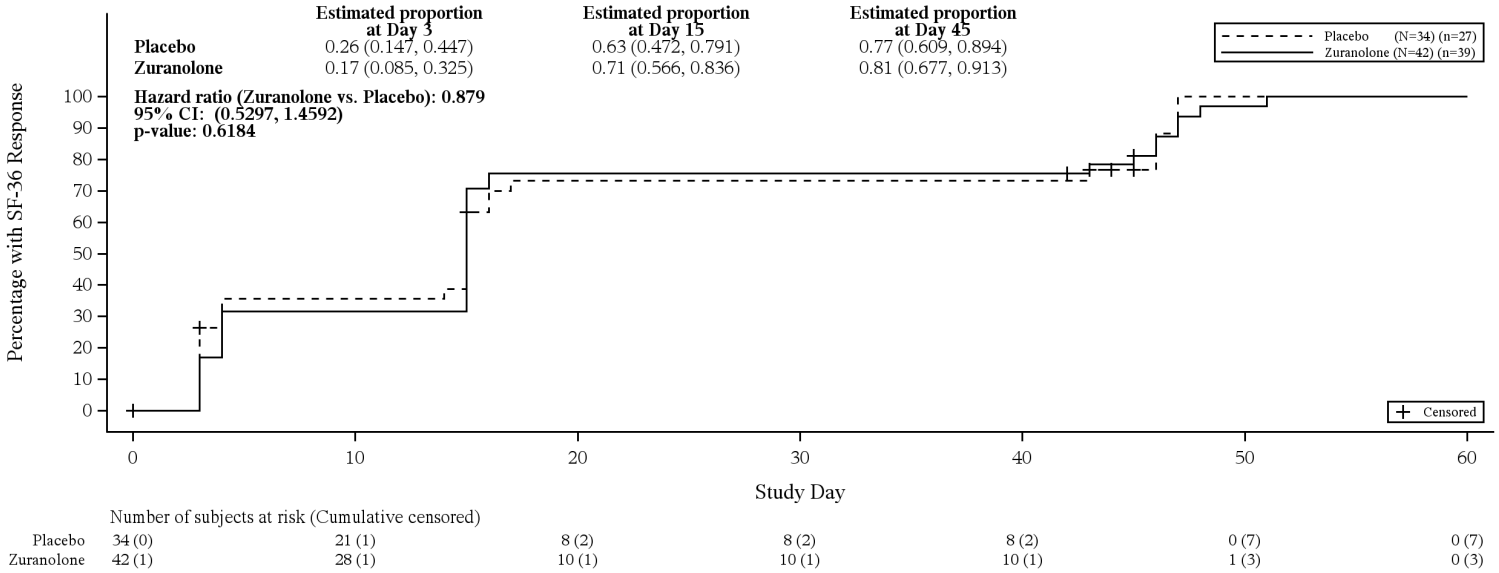
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

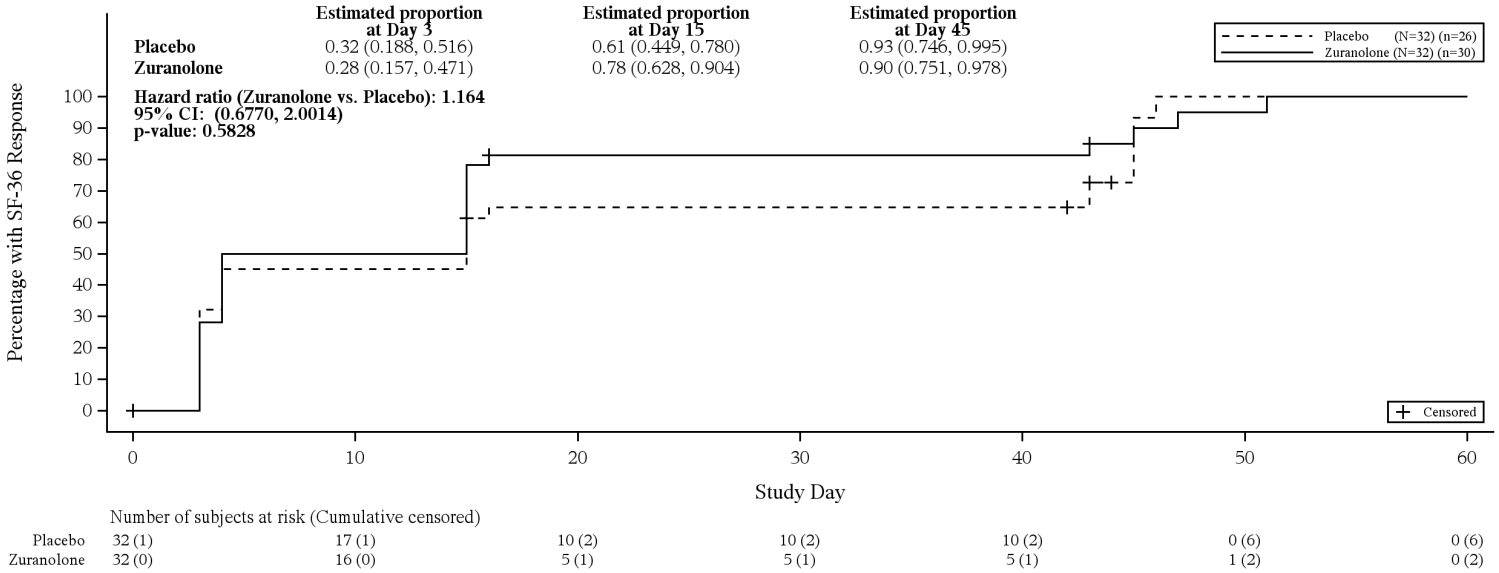
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

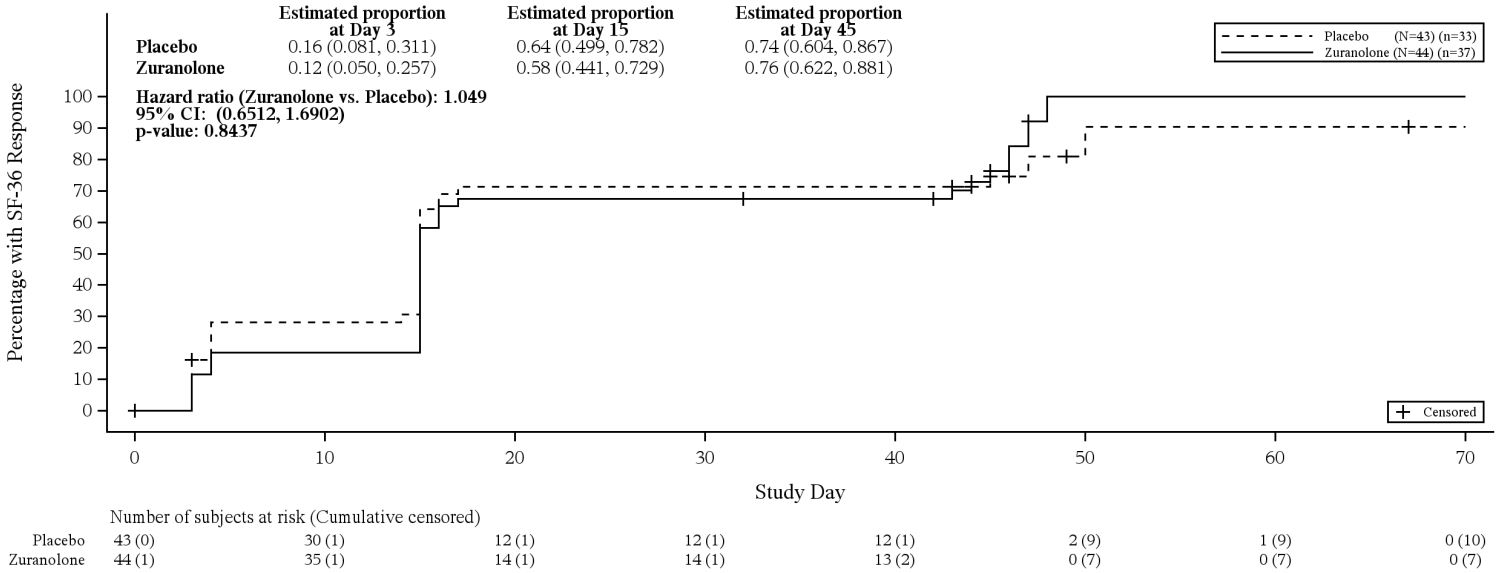
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

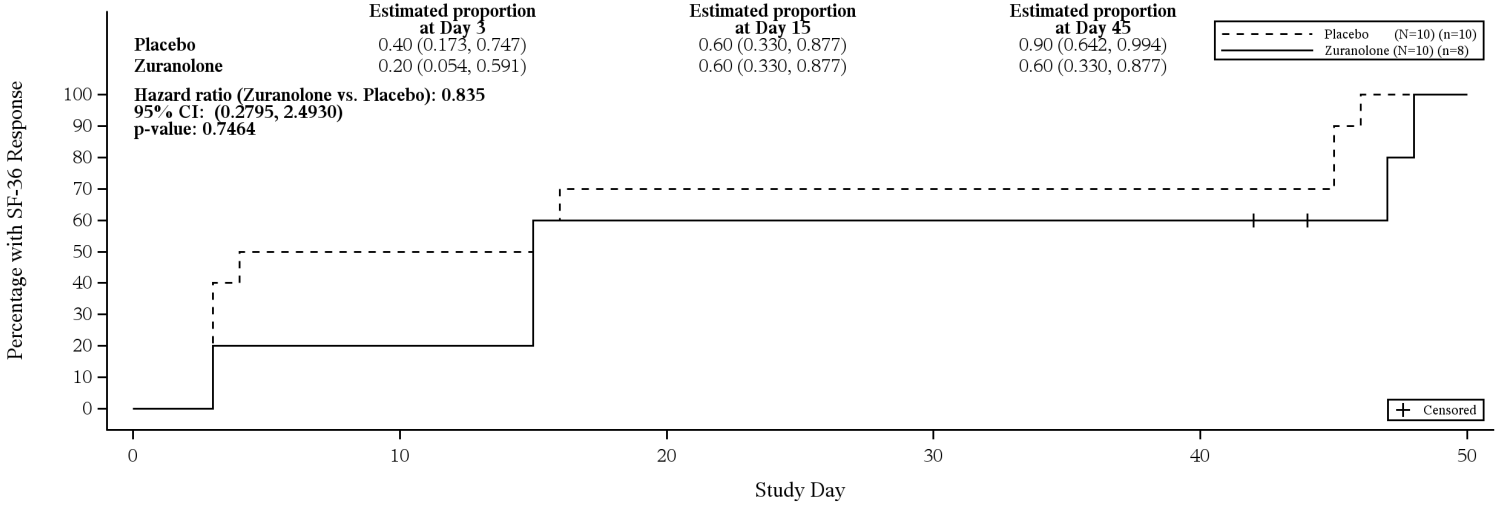
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Number of subjects at risk (Cumulative censored)

Placebo	10 (0)	5 (0)	3 (0)	3 (0)	3 (0)	0 (0)
Zuranolone	10 (0)	8 (0)	4 (0)	4 (0)	4 (0)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

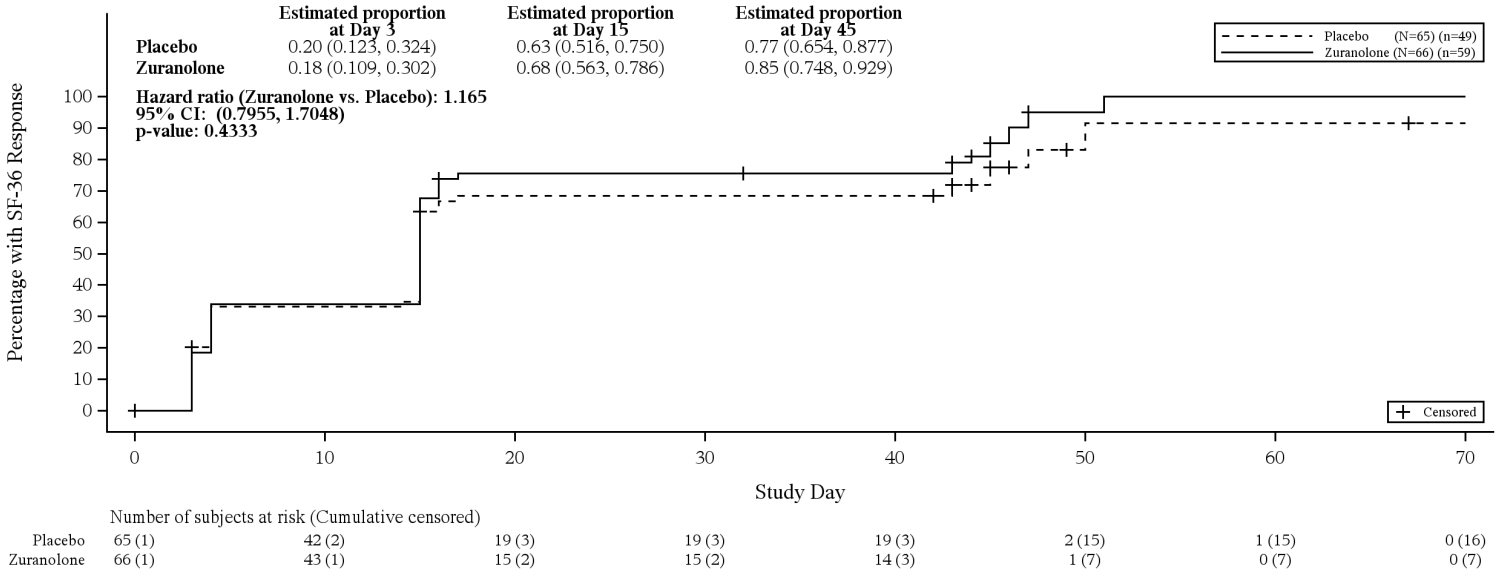
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

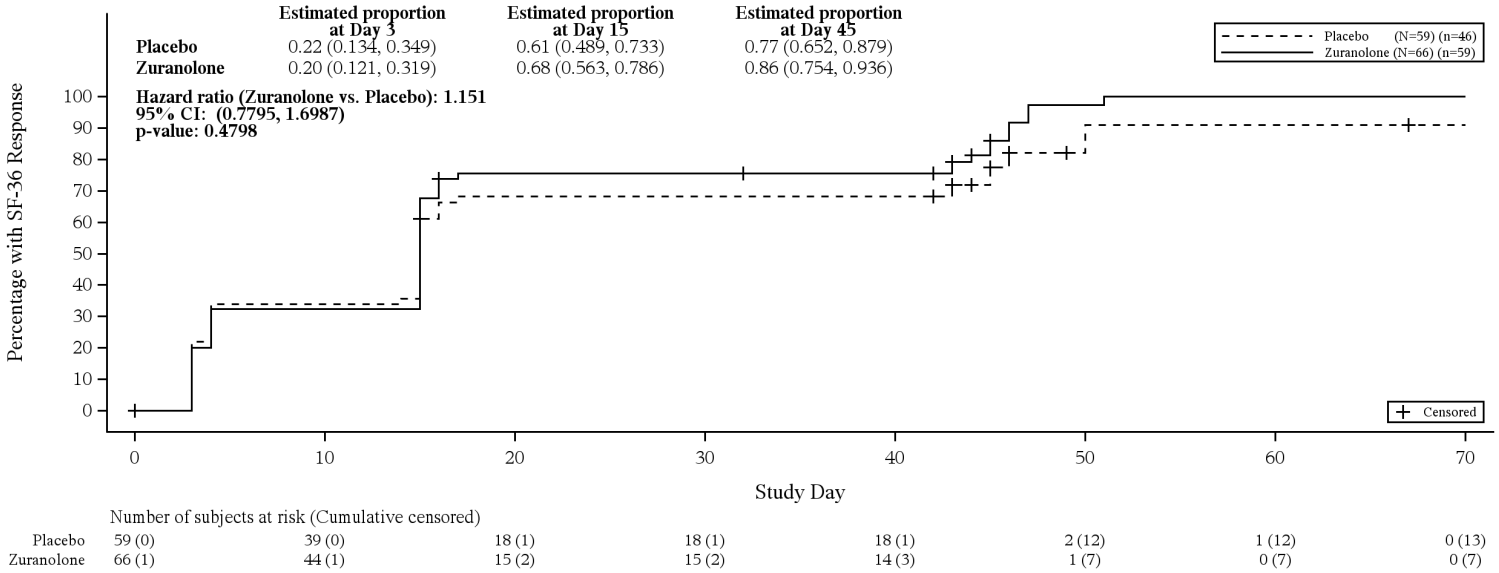
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

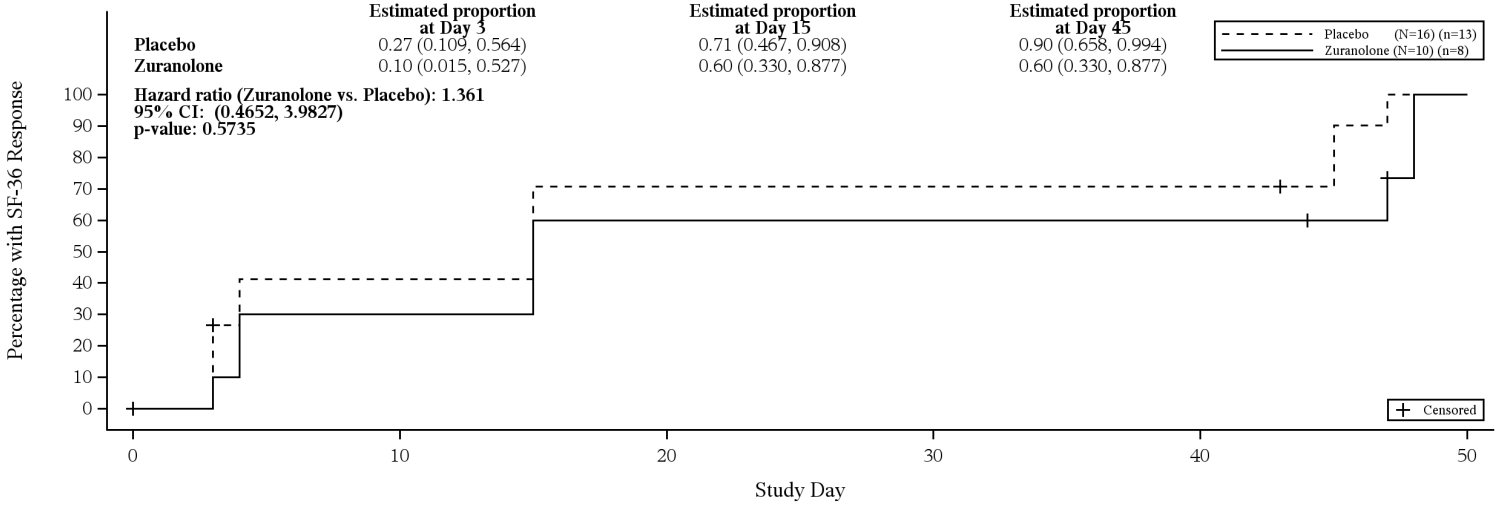
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Number of subjects at risk (Cumulative censored)

Placebo	16 (1)	8 (2)	4 (2)	4 (2)	4 (2)	0 (3)
Zuranolone	10 (0)	7 (0)	4 (0)	4 (0)	4 (0)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-sf-resp15-tte-201-by.sas:f-sf36-sf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

2.8.3 Verschlechterung

2.8.3.1 Responder-Analysen

2.8.3.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with worsening, n (%) [2]	3 (4.0)	0
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.14
95% CI for the RR		(0.007, 2.684)
p-value for RR		0.1925
OR - Odds Ratio (Zuranolone vs. Placebo)		0.14
95% CI for the OR		(0.007, 2.667)
p-value for OR		0.1885
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.04
95% CI for the ARR		(-0.090, 0.011)
p-value for ARR		0.1241

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing SF-36 Social Functioning subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Social Functioning subscale score (for the respective parameter) worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-sf-wors15-201-ovr.sas:t-sf36-sf-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	4 (5.3)	0
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.11
95% CI for the RR		(0.006, 2.002)
p-value for RR		0.1358
OR - Odds Ratio (Zuranolone vs. Placebo)		0.10
95% CI for the OR		(0.005, 1.963)
p-value for OR		0.1310
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.05
95% CI for the ARR		(-0.109, 0.003)
p-value for ARR		0.0651

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.

[1] Number of subjects with non-missing SF-36 Social Functioning subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Social Functioning subscale score (for the respective parameter) worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-sf-wors15-201-ovr.sas:t-sf36-sf-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.8.3.1 .2 Subgruppen

2.8.3.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	3 (4.0)	0	
Number of subjects with response at Day 45, n (%)	4 (5.3)	0	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	0/25	0/17	
25 - 45, n / N (%)	3/50 (6.0)	0/59	
Day 45			
18 - 24, n / N (%)	1/25 (4.0)	0/17	
25 - 45, n / N (%)	3/50 (6.0)	0/59	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-sf-wors15-201-int.sas:t-sf36-sf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	0/22	0/30	
>=28, n / N (%)	3/53 (5.7)	0/46	
Day 45			
<28, n / N (%)	0/22	0/30	
>=28, n / N (%)	4/53 (7.5)	0/46	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	2/32 (6.3)	0/31	
White, n / N (%)	0/40	0/44	
Day 45			
Black or African American, n / N (%)	2/32 (6.3)	0/31	
White, n / N (%)	1/40 (2.5)	0/44	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-sf-wors15-201-int.sas:t-sf36-sf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	3/62 (4.8)	0/60	
Day 45			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	4/62 (6.5)	0/60	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-sf-wors15-201-int.sas:t-sf36-sf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 4 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	0/21	0/13	
25-29.9, n / N (%)	0/20	0/21	
>=30, n / N (%)	3/34 (8.8)	0/42	
Day 45			
<=24.9, n / N (%)	1/21 (4.8)	0/13	
25-29.9, n / N (%)	1/20 (5.0)	0/21	
>=30, n / N (%)	2/34 (5.9)	0/42	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-sf-wors15-201-int.sas:t-sf36-sf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 5 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	2/32 (6.3)	0/32	
Postpartum, n / N (%)	1/43 (2.3)	0/44	
Day 45			
3rd Trimester, n / N (%)	1/32 (3.1)	0/32	
Postpartum, n / N (%)	3/43 (7.0)	0/44	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	1/10 (10.0)	0/10	
No/Unknown, n / N (%)	2/65 (3.1)	0/66	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	4/65 (6.2)	0/66	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-sf-wors15-201-int.sas:t-sf36-sf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Social Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	3/59 (5.1)	0/66	
Recurrent Episode, n / N (%)	0/16	0/10	
Day 45			
1st Episode, n / N (%)	4/59 (6.8)	0/66	
Recurrent Episode, n / N (%)	0/16	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	3/67 (4.5)	0/66	
Day 45			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	4/67 (6.0)	0/66	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-sf-wors15-201-int.sas:t-sf36-sf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

2.8.3.1 .2 .2 Subgruppenanalysen

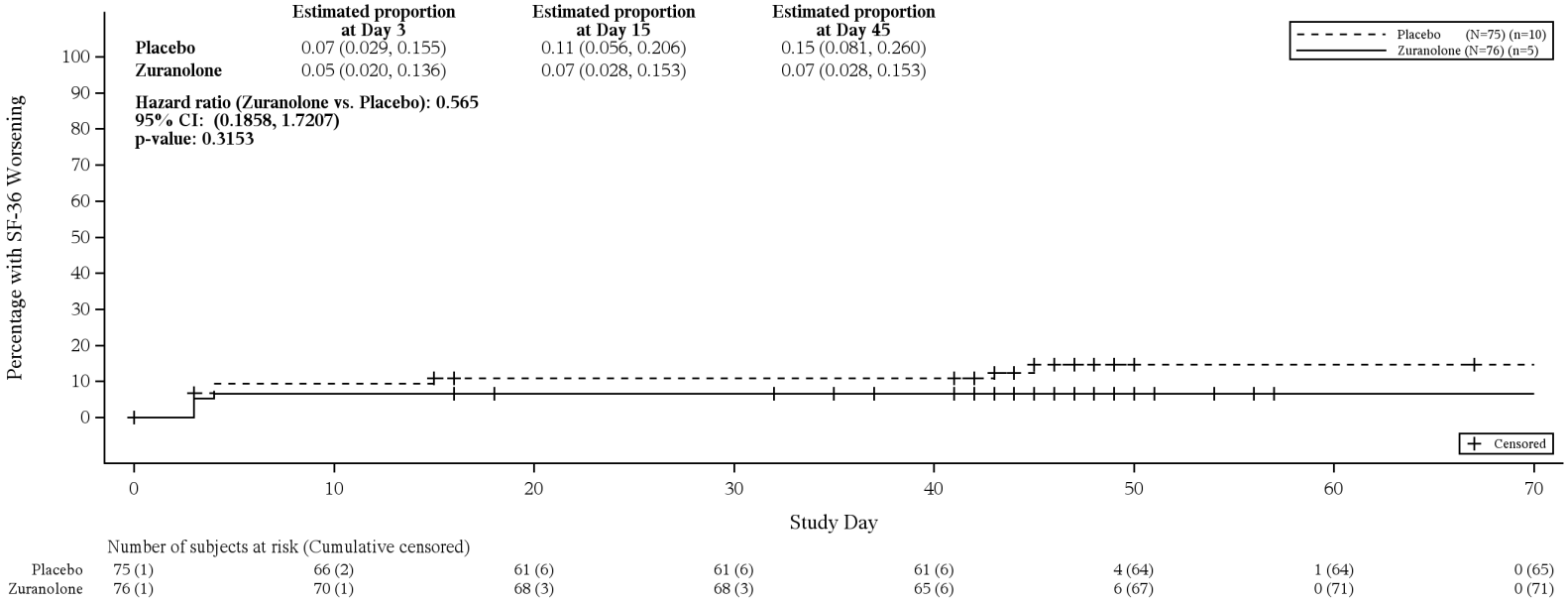
Nicht zutreffend.

2.8.3.2 TTE-Analysen

2.8.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Social Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-sf-wors15-tte-201-ovr.sas:f-sf36-sf-wors15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	10 (13.3)	5 (6.6)
Time to first Social Functioning Subscale worsening (days) [3]		
25th percentile - Q1 (95% CI)	NE (45.0, NE)	NE (NE, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.565
95% CI for the HR		(0.1858 , 1.7207)
p-value for the HR		0.3153

NOTE 1: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) worsening. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-sf-wors15-tte-201-ovr.sas:t-sf36-sf-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.8.3.2 .2 Subgruppen

2.8.3.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	10 (13.3)	5 (6.6)	
Age Group (years)			
18 - 24, n / N (%)	2/25 (8.0)	3/17 (17.6)	NA
25 - 45, n / N (%)	8/50 (16.0)	2/59 (3.4)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	2/22 (9.1)	0/30	NA
>=28, n / N (%)	8/53 (15.1)	5/46 (10.9)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	5/32 (15.6)	3/31 (9.7)	NA
White, n / N (%)	3/40 (7.5)	2/44 (4.5)	
Antidepressant Use at Baseline			
Yes, n / N (%)	1/13 (7.7)	1/16 (6.3)	NA
No, n / N (%)	9/62 (14.5)	4/60 (6.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-sf-wors15-tte-201-int.sas:t-sf36-sf-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Social Functioning Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	2/21 (9.5)	2/13 (15.4)	NA(a)
25-29.9, n / N (%)	2/20 (10.0)	0/21	NA(b)
>=30, n / N (%)	6/34 (17.6)	3/42 (7.1)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	4/32 (12.5)	2/32 (6.3)	NA
Postpartum, n / N (%)	6/43 (14.0)	3/44 (6.8)	
Family History of PPD			
Yes, n / N (%)	1/10 (10.0)	0/10	NA
No/Unknown, n / N (%)	9/65 (13.8)	5/66 (7.6)	
History of PPD			
1st Episode, n / N (%)	9/59 (15.3)	5/66 (7.6)	NA
Recurrent Episode, n / N (%)	1/16 (6.3)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/8	1/10 (10.0)	NA
>=20, n / N (%)	10/67 (14.9)	4/66 (6.1)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-sf-wors15-tte-201-int.sas:t-sf36-sf-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.8.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

2.8.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

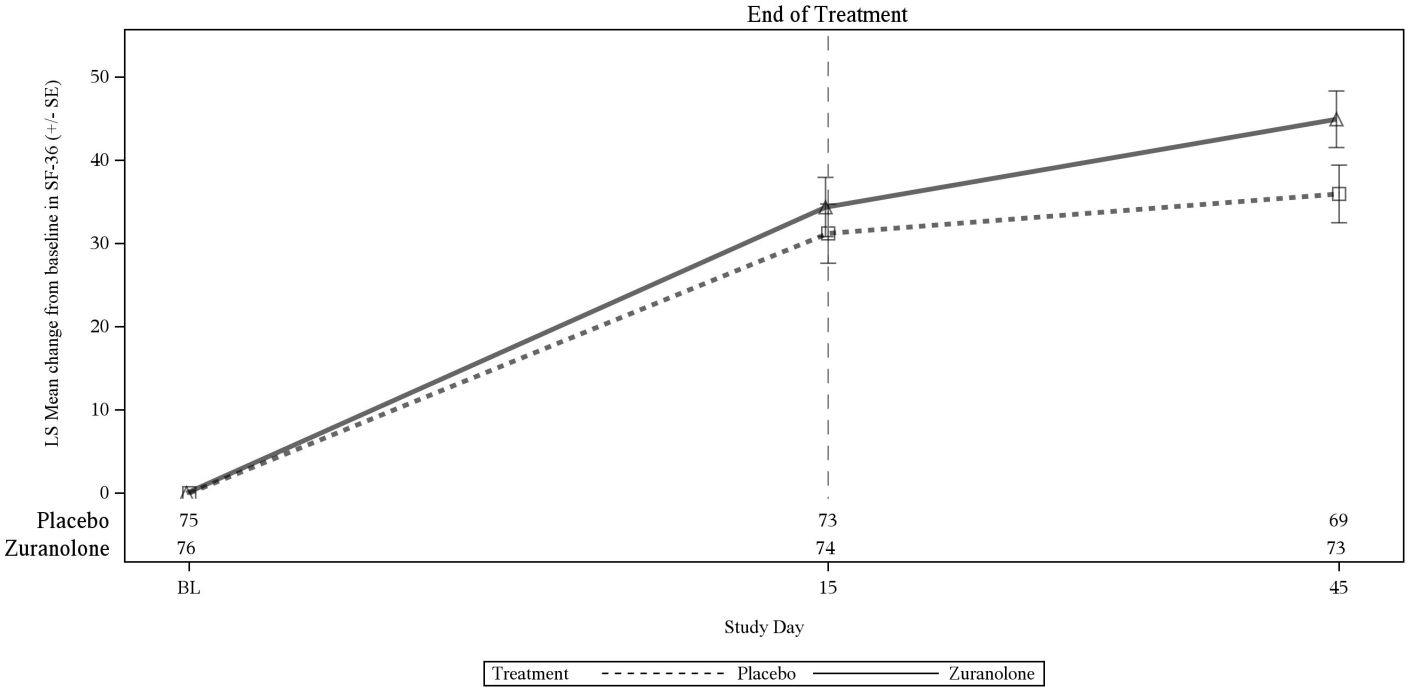
2.9 emotionale Rollenfunktion

2.9.1 MMRM

2.9.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-ovr.sas:f-sf36-re-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale: 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	31.19 (3.584)	34.37 (3.553)
95% CI for the LS Mean	24.11, 38.28	27.35, 41.39
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.18 (5.047)
95% CI for the LS Mean		-6.80, 13.15
p-value		0.5301
Hedges' g (Zuranolone vs. Placebo)		0.103
95% CI for Hedges' g		-0.2202, 0.4268
Day 45		
n	69	73
LS Mean (SE)	35.98 (3.451)	44.93 (3.369)
95% CI for the LS Mean	29.16, 42.80	38.27, 51.59
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.95 (4.825)
95% CI for the LS Mean		-0.59, 18.49
p-value		0.0657
Hedges' g (Zuranolone vs. Placebo)		0.310
95% CI for Hedges' g		-0.0213, 0.6408

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-ovr.sas:t-sf36-re-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.9.1.2 Subgruppen

2.9.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.4718
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.6785
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.9273
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.1744
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-int.sas:t-sf36-re-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.3414(a)
25-29.9	20	21	0.5756(b)
>=30	34	42	0.5844(c)
Onset of PPD			
3rd Trimester	32	32	0.5215
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.4942
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.6822
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-int.sas:t-sf36-re-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

2.9.1.2 .2 Subgruppenanalysen

2.9.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	29.70 (5.713)	36.30 (6.952)
95% CI for the LS Mean	18.14, 41.26	22.23, 50.36
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.60 (9.037)
95% CI for the LS Mean		-11.68, 24.88
p-value		0.4696
Hedges' g (Zuranolone vs. Placebo)		0.225
95% CI for Hedges' g		-0.3928, 0.8432
Day 45		
n	25	16
LS Mean (SE)	28.70 (5.938)	42.92 (7.373)
95% CI for the LS Mean	16.67, 40.72	28.00, 57.84
Difference (Zuranolone - Placebo)		
LS Mean (SE)		14.22 (9.498)
95% CI for the LS Mean		-5.01, 33.45
p-value		0.1426
Hedges' g (Zuranolone vs. Placebo)		0.470
95% CI for Hedges' g		-0.1656, 1.1057

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Age Group: 217-PPD-201B - ITT population

Page: 2 of 2

Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	31.92 (4.615)	33.78 (4.224)
95% CI for the LS Mean	22.77, 41.08	25.40, 42.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.86 (6.266)
95% CI for the LS Mean		-10.57, 14.29
p-value		0.7674
Hedges' g (Zuranolone vs. Placebo)		0.058
95% CI for Hedges' g		-0.3264, 0.4417
Day 45		
n	44	57
LS Mean (SE)	40.00 (4.305)	45.53 (3.818)
95% CI for the LS Mean	31.46, 48.54	37.95, 53.10
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.53 (5.767)
95% CI for the LS Mean		-5.91, 16.97
p-value		0.3399
Hedges' g (Zuranolone vs. Placebo)		0.191
95% CI for Hedges' g		-0.2032, 0.5852

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.9.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 2

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	39.50 (6.787)	37.57 (5.985)
95% CI for the LS Mean	25.82, 53.17	25.52, 49.62
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.93 (9.061)
95% CI for the LS Mean		-20.18, 16.32
p-value		0.8326
Hedges' g (Zuranolone vs. Placebo)		-0.060
95% CI for Hedges' g		-0.6181, 0.4989
Day 45		
n	22	28
LS Mean (SE)	41.77 (6.603)	48.78 (5.821)
95% CI for the LS Mean	28.48, 55.06	37.07, 60.49
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.01 (8.814)
95% CI for the LS Mean		-10.72, 24.74
p-value		0.4305
Hedges' g (Zuranolone vs. Placebo)		0.223
95% CI for Hedges' g		-0.3371, 0.7831

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 2 of 2

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	27.65 (4.223)	32.23 (4.448)
95% CI for the LS Mean	19.26, 36.03	23.40, 41.07
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.59 (6.141)
95% CI for the LS Mean		-7.61, 16.78
p-value		0.4570
Hedges' g (Zuranolone vs. Placebo)		0.151
95% CI for Hedges' g		-0.2484, 0.5498
Day 45		
n	47	45
LS Mean (SE)	33.48 (4.079)	42.43 (4.200)
95% CI for the LS Mean	25.38, 41.58	34.08, 50.77
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.95 (5.866)
95% CI for the LS Mean		-2.70, 20.60
p-value		0.1305
Hedges' g (Zuranolone vs. Placebo)		0.316
95% CI for Hedges' g		-0.0958, 0.7269

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.9.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	27.04 (5.892)	31.39 (5.888)
95% CI for the LS Mean	15.25, 38.83	19.61, 43.17
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.36 (8.338)
95% CI for the LS Mean		-12.33, 21.04
p-value		0.6033
Hedges' g (Zuranolone vs. Placebo)		0.131
95% CI for Hedges' g		-0.3673, 0.6294
Day 45		
n	30	30
LS Mean (SE)	34.96 (5.421)	41.34 (5.422)
95% CI for the LS Mean	24.11, 45.81	30.49, 52.19
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.38 (7.675)
95% CI for the LS Mean		-8.98, 21.75
p-value		0.4090
Hedges' g (Zuranolone vs. Placebo)		0.212
95% CI for Hedges' g		-0.2955, 0.7194

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Race Group: 217-PPD-201B - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	34.43 (4.748)	36.37 (4.555)
95% CI for the LS Mean	24.97, 43.89	27.30, 45.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.94 (6.579)
95% CI for the LS Mean		-11.16, 15.04
p-value		0.7689
Hedges' g (Zuranolone vs. Placebo)		0.065
95% CI for Hedges' g		-0.3710, 0.5009
Day 45		
n	36	42
LS Mean (SE)	37.18 (4.750)	46.64 (4.443)
95% CI for the LS Mean	27.73, 46.64	37.79, 55.49
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.46 (6.504)
95% CI for the LS Mean		-3.50, 22.41
p-value		0.1501
Hedges' g (Zuranolone vs. Placebo)		0.327
95% CI for Hedges' g		-0.1212, 0.7750

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.9.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	26.78 (8.398)	45.71 (7.810)
95% CI for the LS Mean	9.49, 44.06	29.63, 61.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		18.93 (11.572)
95% CI for the LS Mean		-4.88, 42.75
p-value		0.1142
Hedges' g (Zuranolone vs. Placebo)		0.602
95% CI for Hedges' g		-0.1574, 1.3611
Day 45		
n	11	15
LS Mean (SE)	38.27 (9.416)	52.93 (8.242)
95% CI for the LS Mean	18.86, 57.69	35.86, 70.00
Difference (Zuranolone - Placebo)		
LS Mean (SE)		14.66 (12.618)
95% CI for the LS Mean		-11.39, 40.71
p-value		0.2569
Hedges' g (Zuranolone vs. Placebo)		0.447
95% CI for Hedges' g		-0.3409, 1.2340

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 2 of 2

Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	32.24 (3.960)	31.45 (3.984)
95% CI for the LS Mean	24.40, 40.09	23.56, 39.34
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.79 (5.618)
95% CI for the LS Mean		-11.92, 10.33
p-value		0.8878
Hedges' g (Zuranolone vs. Placebo)		-0.026
95% CI for Hedges' g		-0.3851, 0.3336
Day 45		
n	58	58
LS Mean (SE)	35.77 (3.713)	42.89 (3.713)
95% CI for the LS Mean	28.42, 43.12	35.54, 50.24
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.12 (5.251)
95% CI for the LS Mean		-3.28, 17.52
p-value		0.1777
Hedges' g (Zuranolone vs. Placebo)		0.250
95% CI for Hedges' g		-0.1152, 0.6155

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.9.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population
Page: 1 of 3
BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	31.50 (6.139)	40.71 (7.632)
95% CI for the LS Mean	18.95, 44.04	25.11, 56.31
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.21 (9.812)
95% CI for the LS Mean		-10.84, 29.26
p-value		0.3555
Hedges' g (Zuranolone vs. Placebo)		0.326
95% CI for Hedges' g		-0.3764, 1.0289
Day 45		
n	18	12
LS Mean (SE)	31.26 (6.956)	46.91 (8.557)
95% CI for the LS Mean	17.03, 45.49	29.40, 64.42
Difference (Zuranolone - Placebo)		
LS Mean (SE)		15.65 (11.070)
95% CI for the LS Mean		-6.98, 38.28
p-value		0.1680
Hedges' g (Zuranolone vs. Placebo)		0.513
95% CI for Hedges' g		-0.2292, 1.2545

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	34.75 (8.272)	31.22 (8.170)
95% CI for the LS Mean	17.97, 51.53	14.66, 47.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.53 (11.632)
95% CI for the LS Mean		-27.12, 20.05
p-value		0.7632
Hedges' g (Zuranolone vs. Placebo)		-0.094
95% CI for Hedges' g		-0.7142, 0.5260
Day 45		
n	20	20
LS Mean (SE)	39.75 (7.369)	43.70 (7.278)
95% CI for the LS Mean	24.81, 54.70	28.96, 58.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.95 (10.364)
95% CI for the LS Mean		-17.06, 24.95
p-value		0.7056
Hedges' g (Zuranolone vs. Placebo)		0.118
95% CI for Hedges' g		-0.5023, 0.7384

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	28.91 (5.042)	33.54 (4.525)
95% CI for the LS Mean	18.86, 38.97	24.52, 42.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.63 (6.775)
95% CI for the LS Mean		-8.88, 18.14
p-value		0.4969
Hedges' g (Zuranolone vs. Placebo)		0.158
95% CI for Hedges' g		-0.3010, 0.6171
Day 45		
n	31	41
LS Mean (SE)	36.28 (4.844)	44.72 (4.233)
95% CI for the LS Mean	26.62, 45.94	36.27, 53.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.43 (6.435)
95% CI for the LS Mean		-4.40, 21.27
p-value		0.1943
Hedges' g (Zuranolone vs. Placebo)		0.309
95% CI for Hedges' g		-0.1606, 0.7778

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.9.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	27.22 (5.706)	33.15 (5.613)
95% CI for the LS Mean	15.81, 38.64	21.93, 44.38
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.93 (8.013)
95% CI for the LS Mean		-10.10, 21.96
p-value		0.4622
Hedges' g (Zuranolone vs. Placebo)		0.184
95% CI for Hedges' g		-0.3108, 0.6791
Day 45		
n	29	30
LS Mean (SE)	32.44 (5.457)	44.36 (5.367)
95% CI for the LS Mean	21.52, 43.37	33.61, 55.10
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.92 (7.662)
95% CI for the LS Mean		-3.42, 27.26
p-value		0.1253
Hedges' g (Zuranolone vs. Placebo)		0.400
95% CI for Hedges' g		-0.1158, 0.9152

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	34.38 (4.568)	35.14 (4.556)
95% CI for the LS Mean	25.28, 43.47	26.07, 44.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.76 (6.460)
95% CI for the LS Mean		-12.10, 13.62
p-value		0.9066
Hedges' g (Zuranolone vs. Placebo)		0.025
95% CI for Hedges' g		-0.4023, 0.4532
Day 45		
n	40	43
LS Mean (SE)	38.81 (4.546)	45.11 (4.412)
95% CI for the LS Mean	29.77, 47.86	36.33, 53.89
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.30 (6.345)
95% CI for the LS Mean		-6.33, 18.93
p-value		0.3239
Hedges' g (Zuranolone vs. Placebo)		0.216
95% CI for Hedges' g		-0.2158, 0.6478

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.9.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	30.40 (8.565)	34.57 (8.584)
95% CI for the LS Mean	12.37, 48.44	16.50, 52.64
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.17 (12.476)
95% CI for the LS Mean		-22.04, 30.38
p-value		0.7422
Hedges' g (Zuranolone vs. Placebo)		0.143
95% CI for Hedges' g		-0.7346, 1.0207
Day 45		
n	9	10
LS Mean (SE)	50.03 (7.910)	38.74 (7.486)
95% CI for the LS Mean	33.32, 66.74	22.84, 54.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-11.29 (11.351)
95% CI for the LS Mean		-35.27, 12.68
p-value		0.3339
Hedges' g (Zuranolone vs. Placebo)		-0.437
95% CI for Hedges' g		-1.3479, 0.4745

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	31.45 (3.964)	34.08 (3.923)
95% CI for the LS Mean	23.60, 39.30	26.32, 41.85
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.63 (5.579)
95% CI for the LS Mean		-8.41, 13.68
p-value		0.6376
Hedges' g (Zuranolone vs. Placebo)		0.083
95% CI for Hedges' g		-0.2647, 0.4313
Day 45		
n	60	63
LS Mean (SE)	34.01 (3.801)	45.66 (3.719)
95% CI for the LS Mean	26.48, 41.53	38.30, 53.03
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.66 (5.318)
95% CI for the LS Mean		1.13, 22.18
p-value		0.0303
Hedges' g (Zuranolone vs. Placebo)		0.393
95% CI for Hedges' g		0.0359, 0.7498

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.9.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	33.48 (3.967)	35.48 (3.800)
95% CI for the LS Mean	25.62, 41.33	27.96, 43.01
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.00 (5.494)
95% CI for the LS Mean		-8.87, 12.88
p-value		0.7159
Hedges' g (Zuranolone vs. Placebo)		0.065
95% CI for Hedges' g		-0.2884, 0.4193
Day 45		
n	55	64
LS Mean (SE)	37.56 (3.937)	45.59 (3.678)
95% CI for the LS Mean	29.76, 45.36	38.31, 52.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.03 (5.388)
95% CI for the LS Mean		-2.64, 18.70
p-value		0.1387
Hedges' g (Zuranolone vs. Placebo)		0.272
95% CI for Hedges' g		-0.0897, 0.6344

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	21.48 (8.834)	27.56 (10.469)
95% CI for the LS Mean	3.03, 39.94	5.70, 49.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.08 (13.946)
95% CI for the LS Mean		-23.01, 35.17
p-value		0.6674
Hedges' g (Zuranolone vs. Placebo)		0.174
95% CI for Hedges' g		-0.6386, 0.9873
Day 45		
n	14	9
LS Mean (SE)	29.22 (7.657)	40.94 (9.521)
95% CI for the LS Mean	13.21, 45.23	21.13, 60.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.72 (12.558)
95% CI for the LS Mean		-14.42, 37.86
p-value		0.3614
Hedges' g (Zuranolone vs. Placebo)		0.384
95% CI for Hedges' g		-0.4604, 1.2291

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

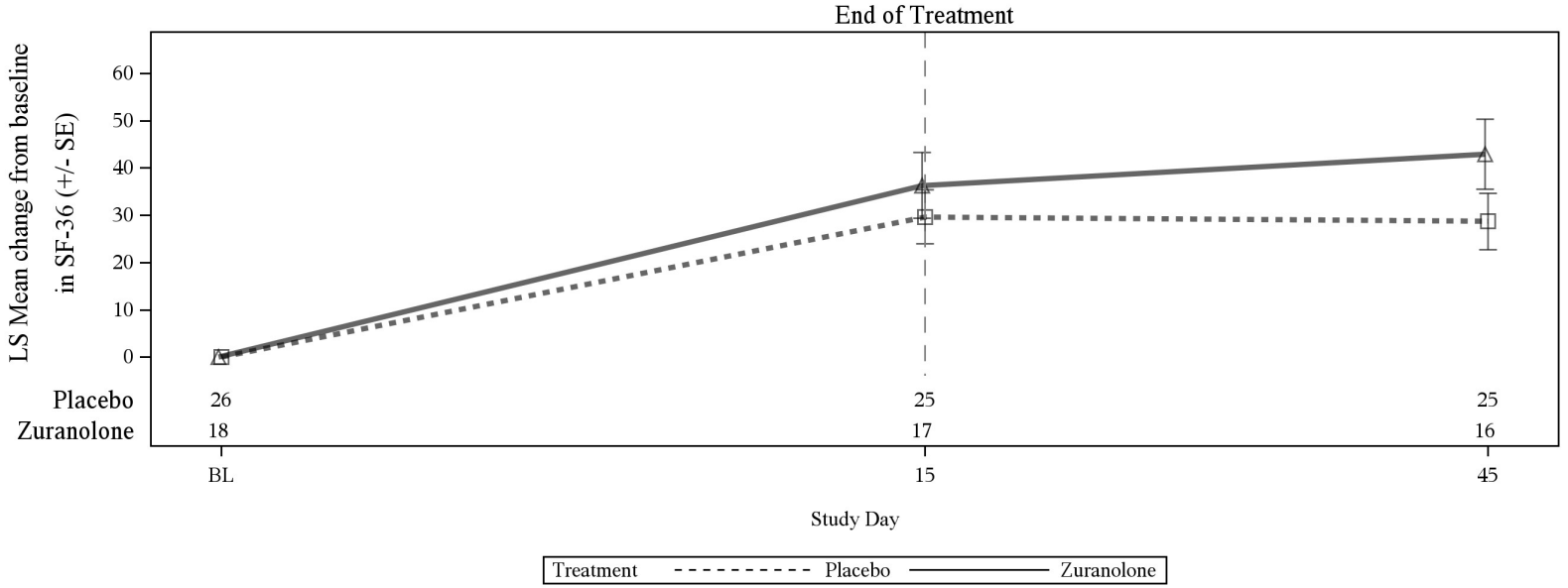
Source: biib125/v_a/germany_amnog/t-sf36-re-mmrm-201-by.sas:t-sf36-re-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.9.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

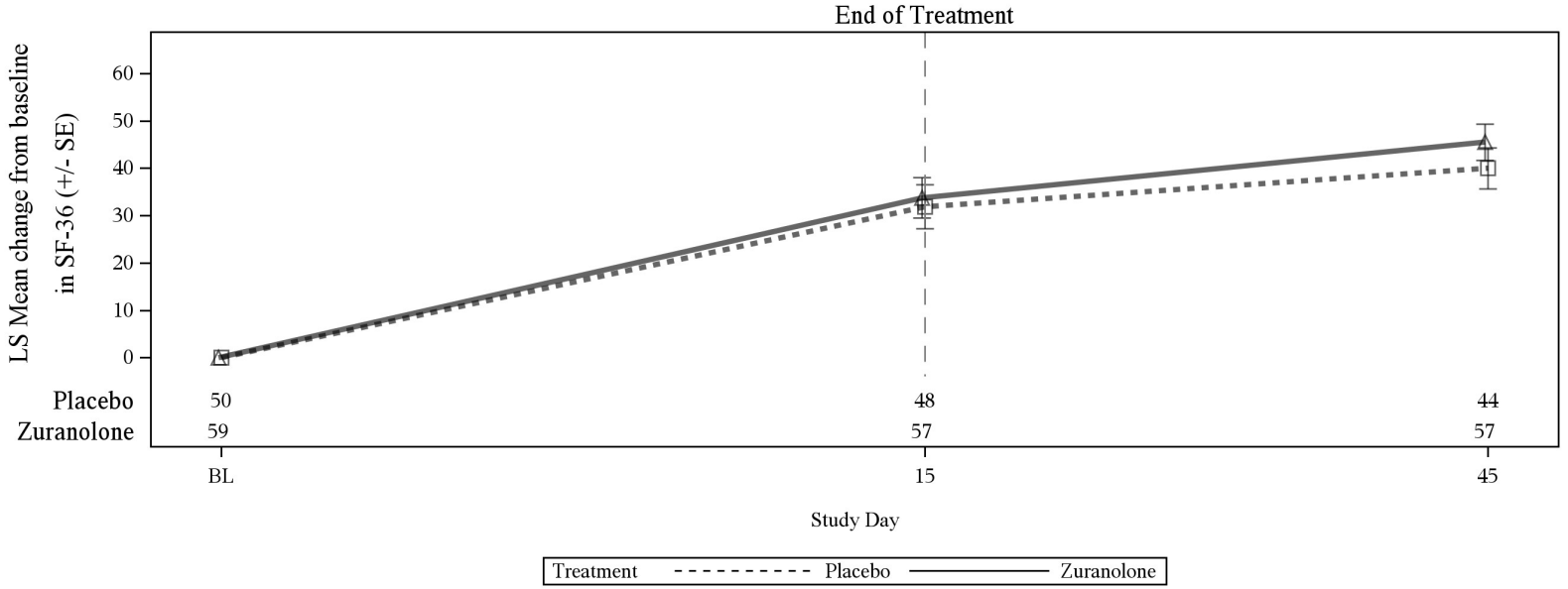
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

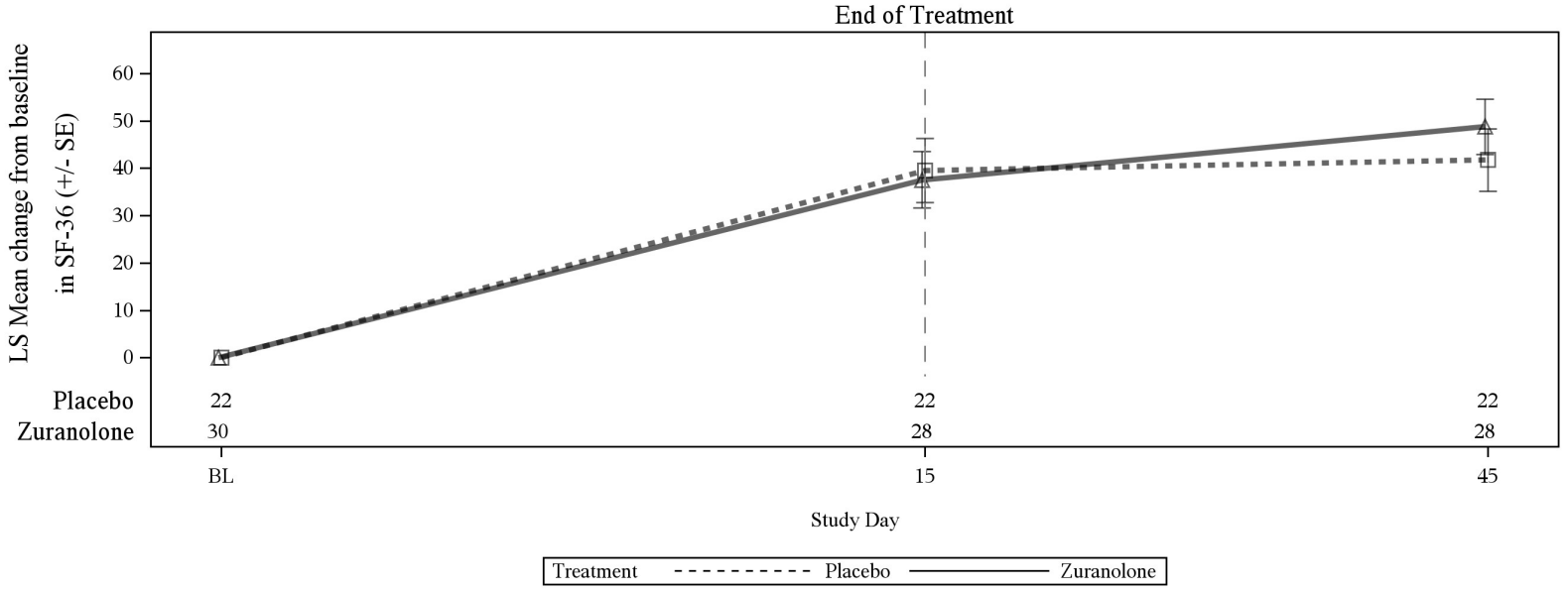
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

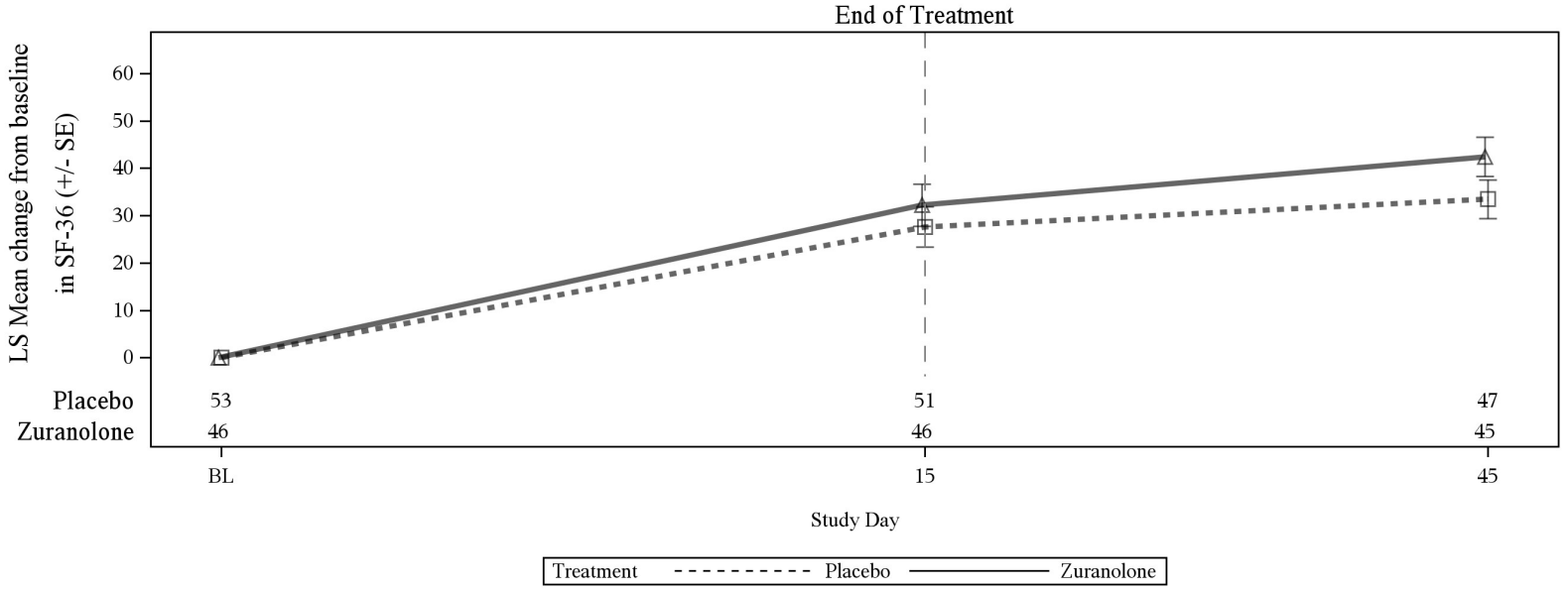
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

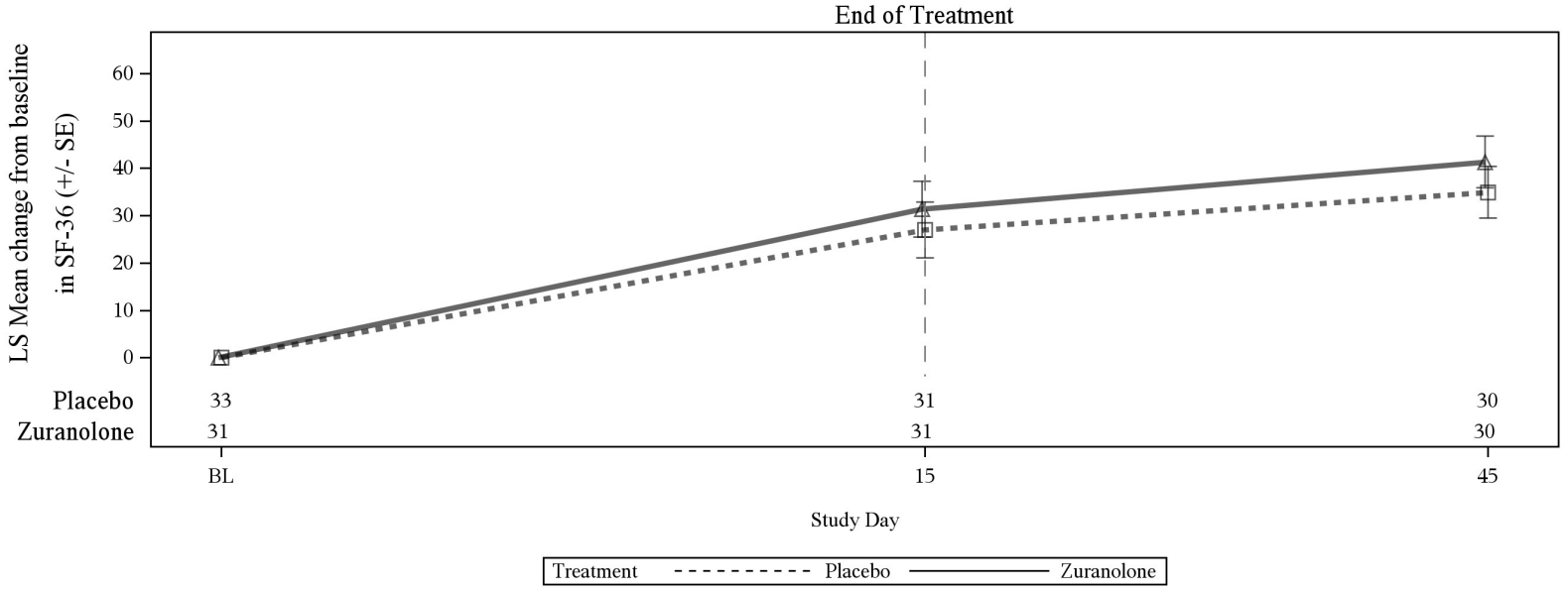
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

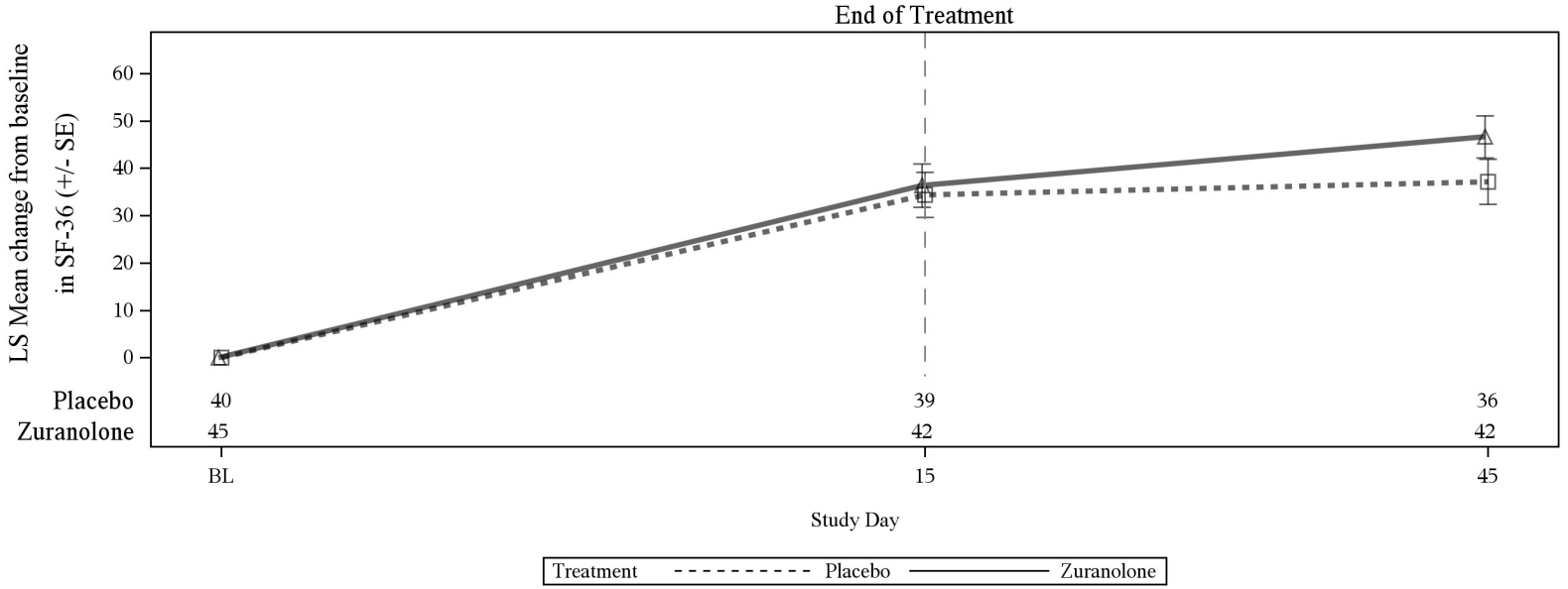
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

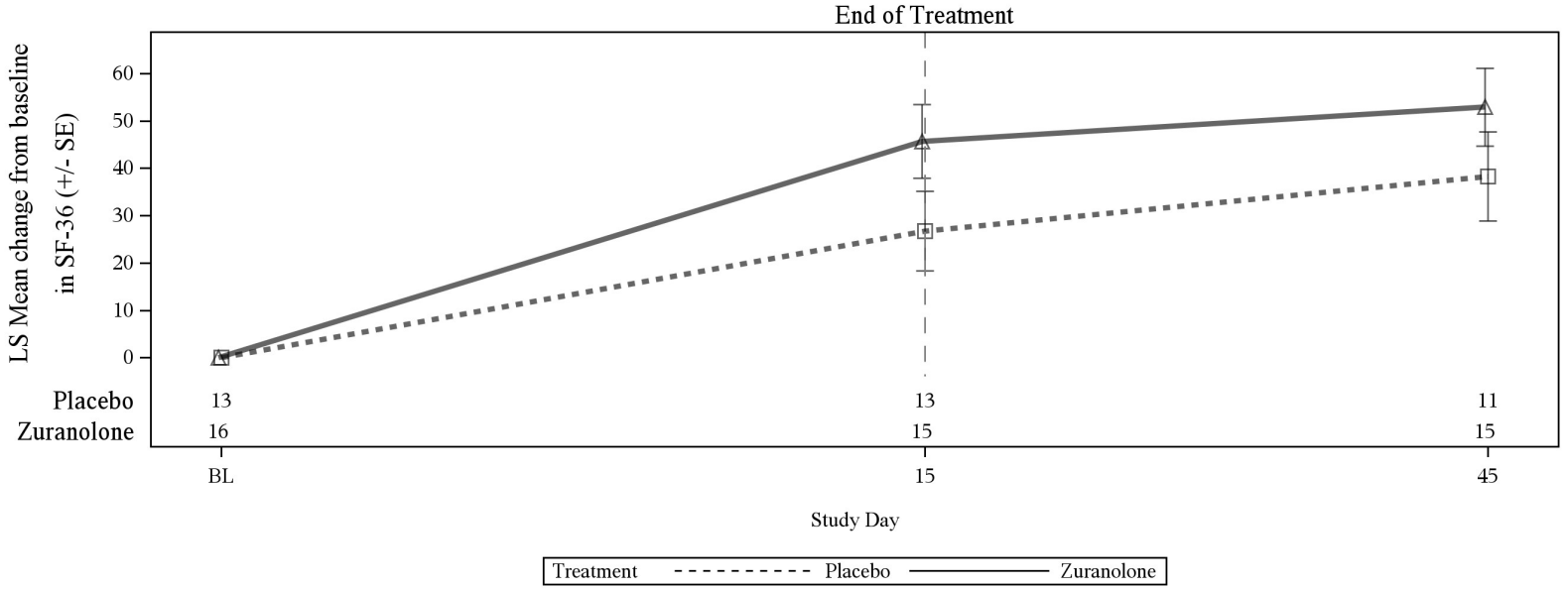
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 7 of 17

Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

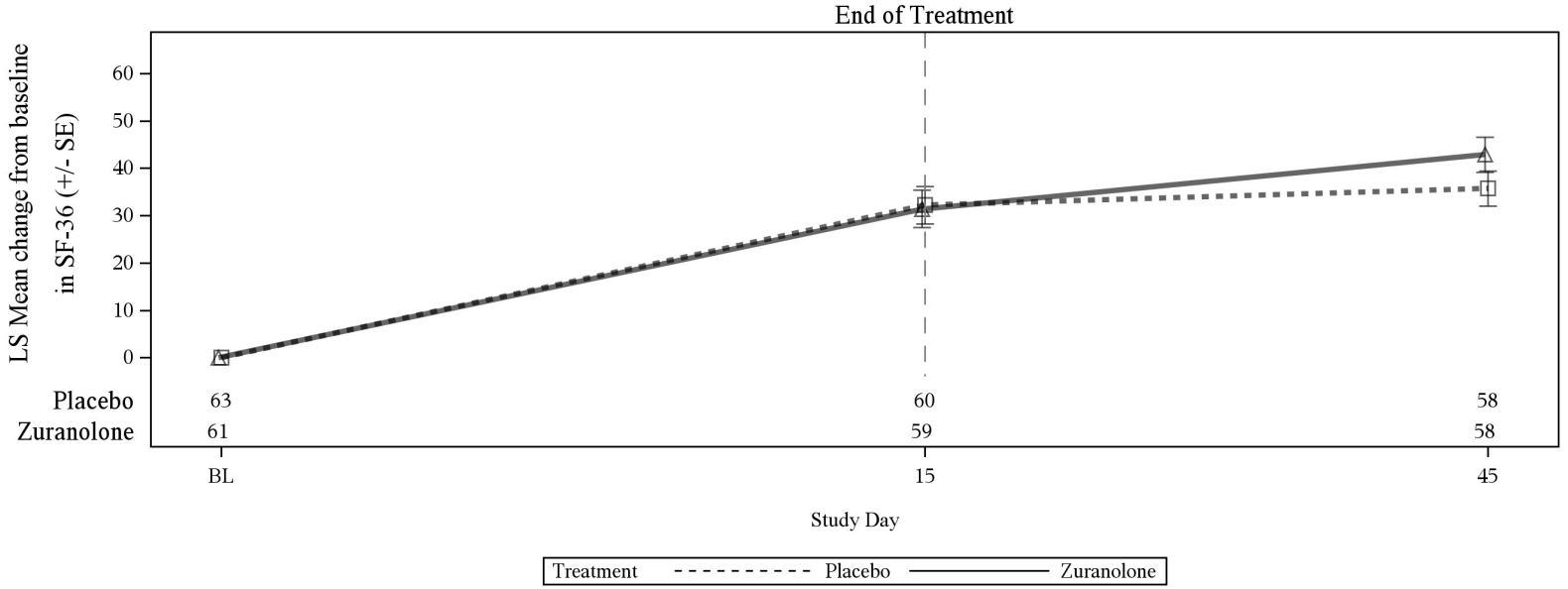
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

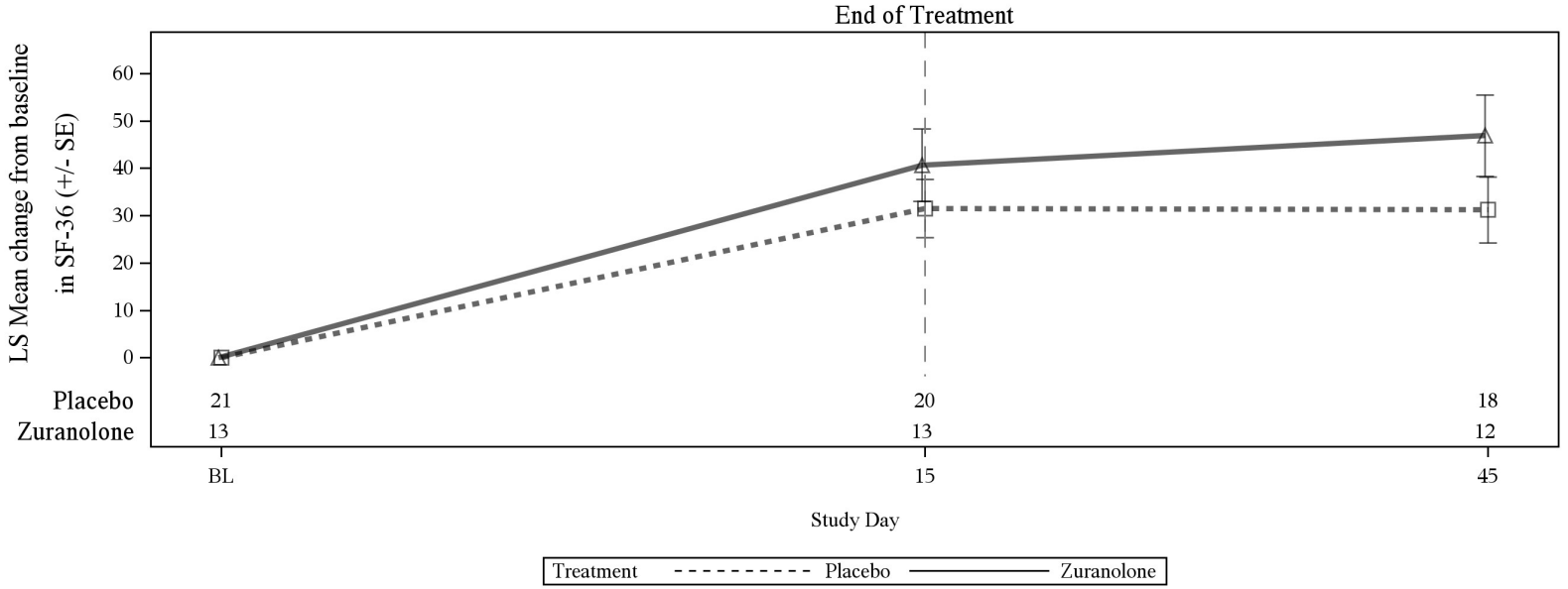
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 9 of 17

BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

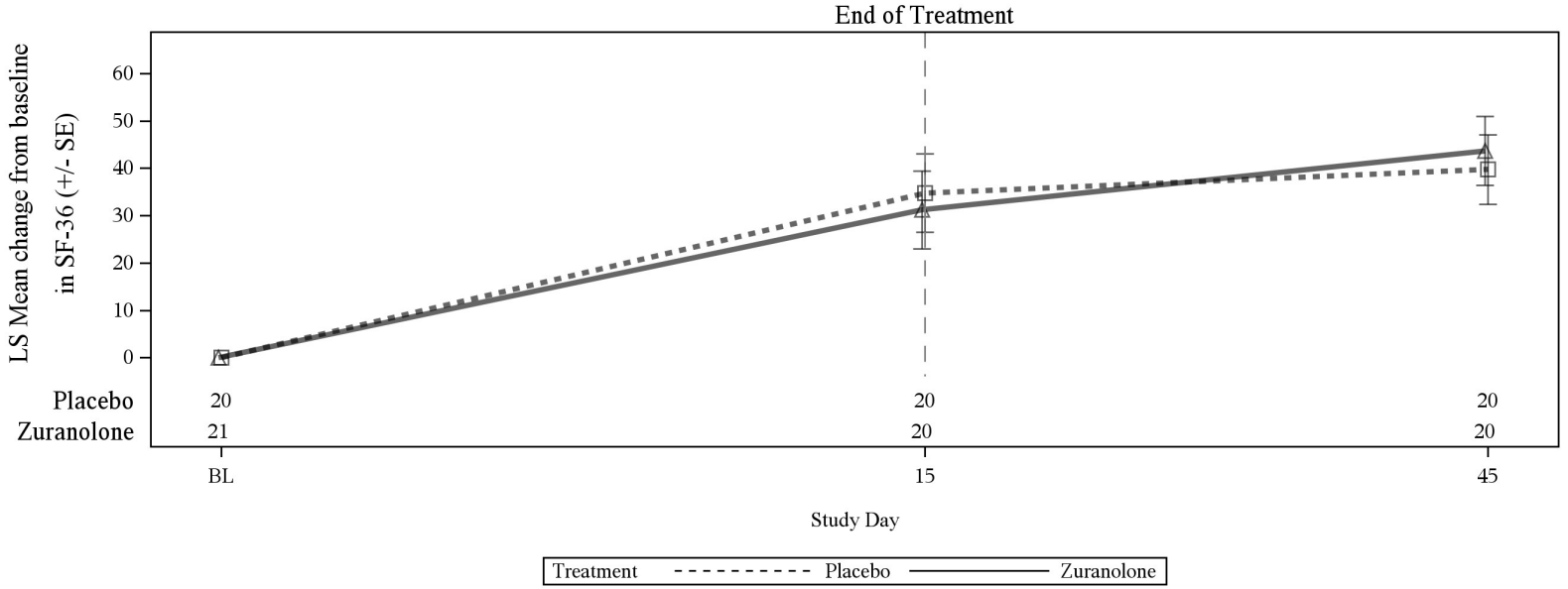
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

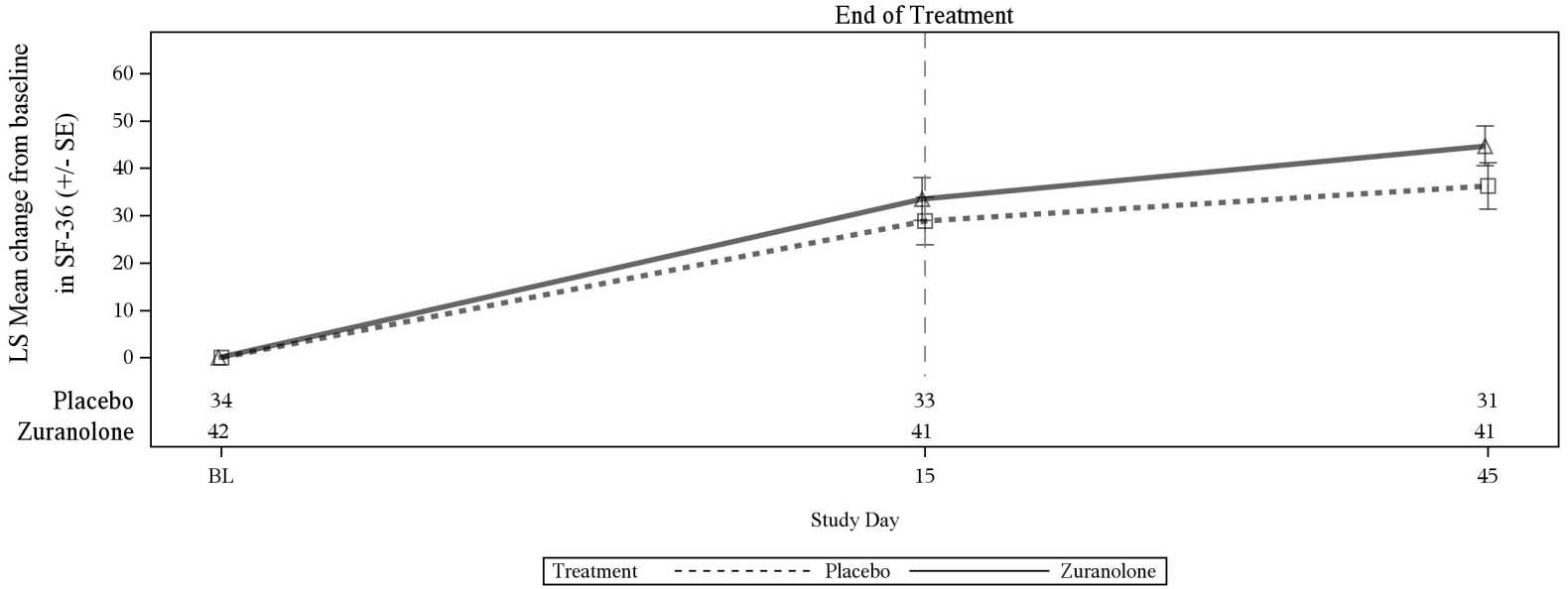
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 11 of 17

BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

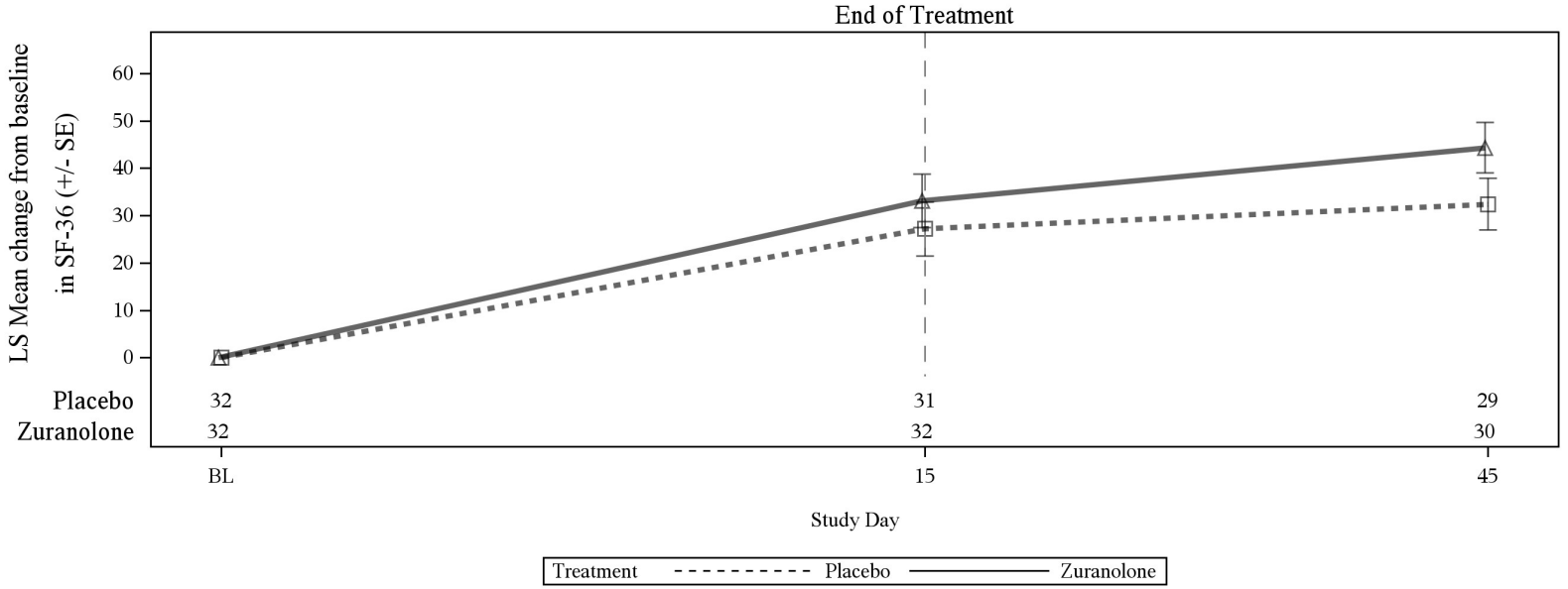
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 12 of 17

Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

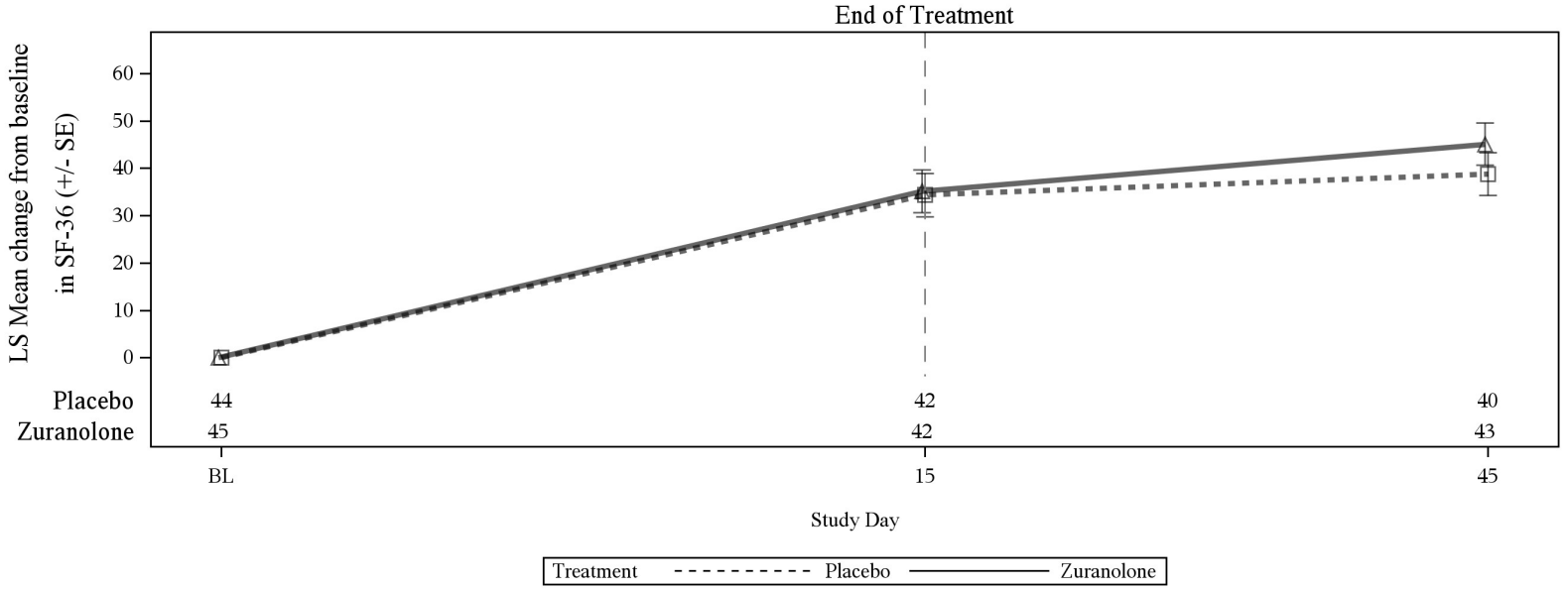
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 13 of 17

Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

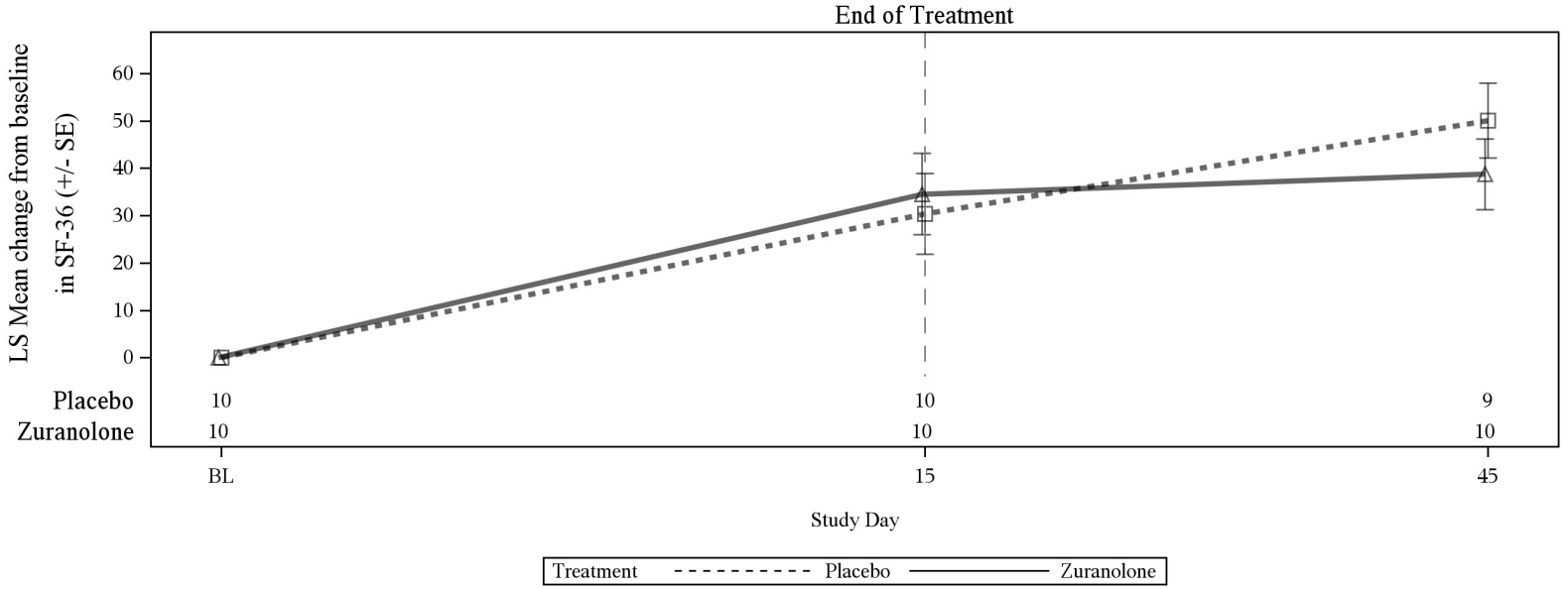
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 14 of 17

Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

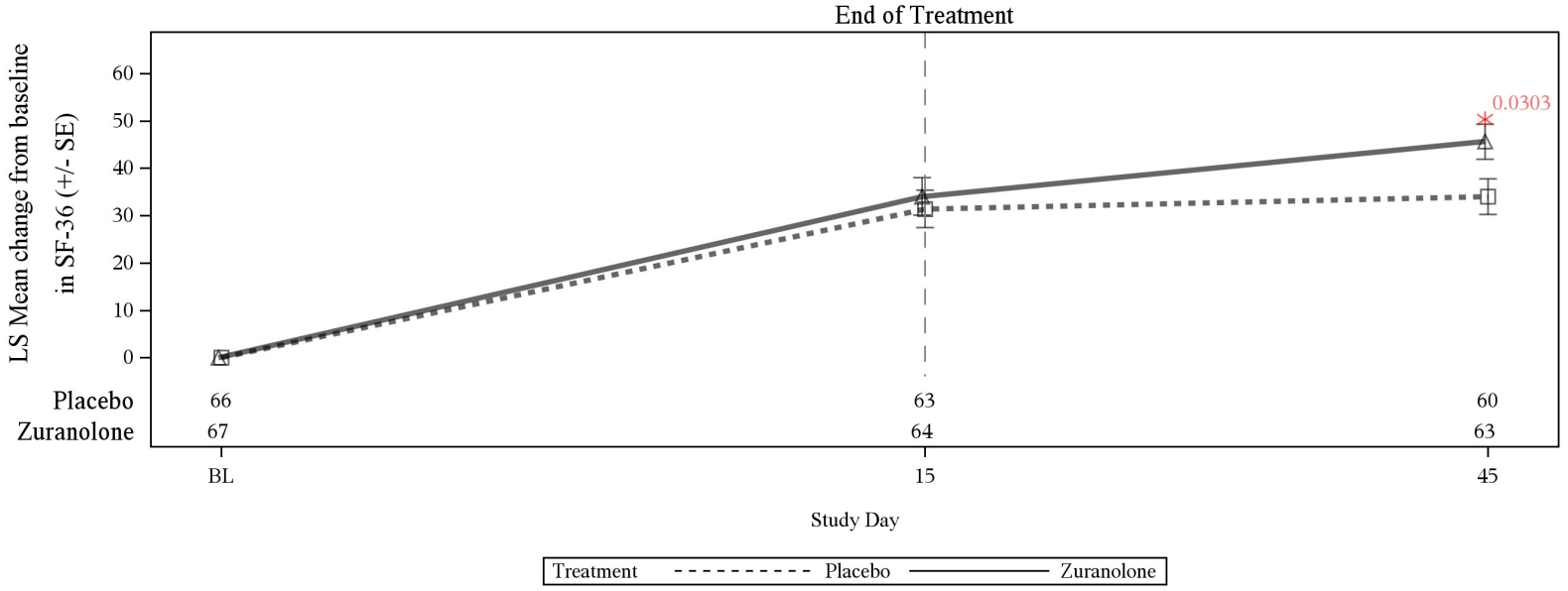
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 15 of 17

Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

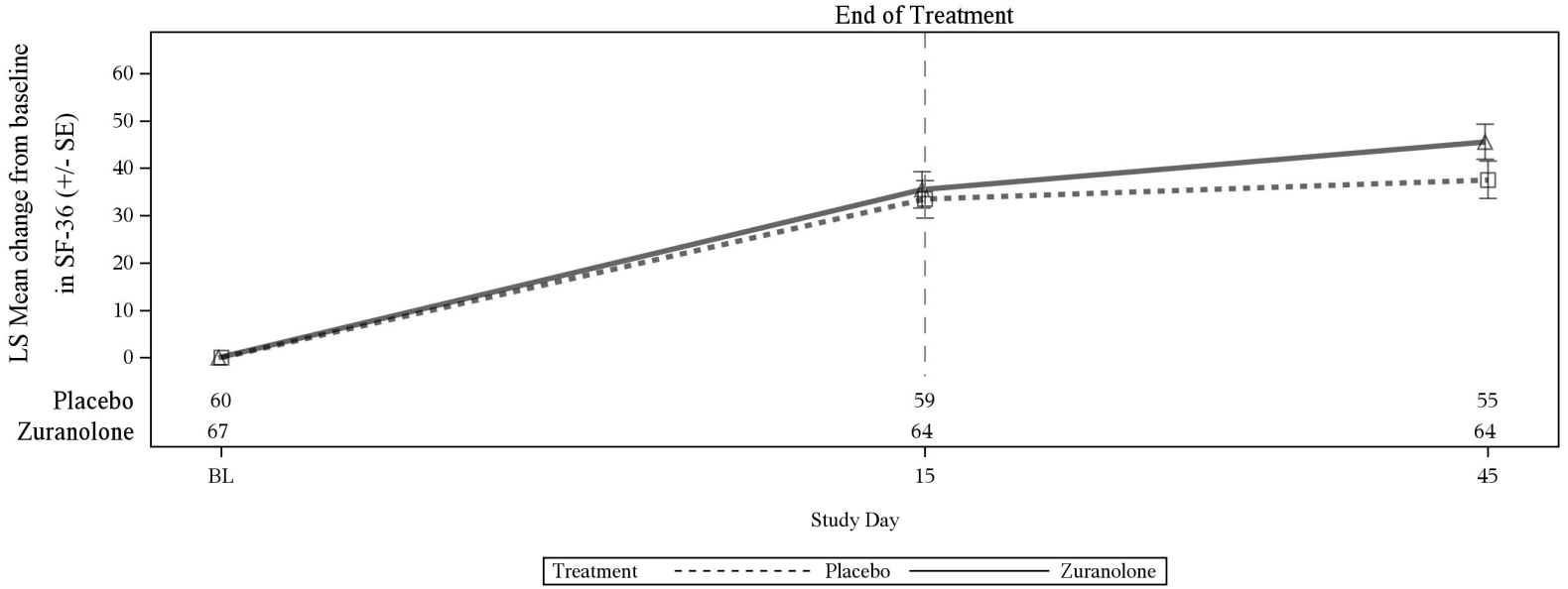
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Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 16 of 17

History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

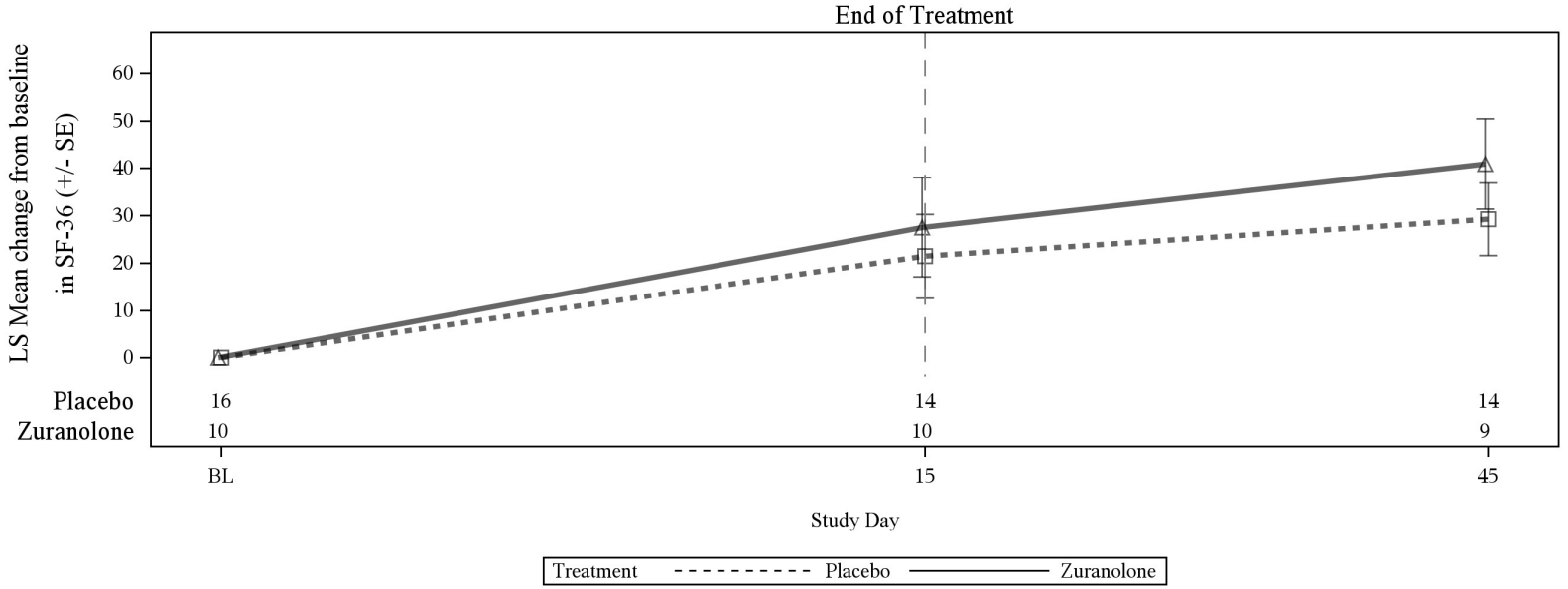
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Role-Emotional Subscale by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-re-mmrm-201-by.sas:f-sf36-re-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

2.9.2 Ansprechen

2.9.2.1 Responder-Analysen

2.9.2.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with a response, n (%) [2]	54 (72.0)	53 (69.7)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.977
95% CI for the RR		(0.802, 1.191)
p-value for RR		0.8206
OR - Odds Ratio (Zuranolone vs. Placebo)		0.903
95% CI for the OR		(0.441, 1.846)
p-value for OR		0.7788
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.017
95% CI for the ARR		(-0.160, 0.126)
p-value for ARR		0.8151

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.
[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-ovr.sas:t-sf36-re-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	51 (68.0)	57 (75.0)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.107
95% CI for the RR		(0.912, 1.343)
p-value for RR		0.3041
OR - Odds Ratio (Zuranolone vs. Placebo)		1.437
95% CI for the OR		(0.698, 2.958)
p-value for OR		0.3256
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.074
95% CI for the ARR		(-0.066, 0.215)
p-value for ARR		0.3001

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-ovr.sas:t-sf36-re-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.9.2.1 .2 Subgruppen

2.9.2.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	54 (72.0)	53 (69.7)	
Number of subjects with response at Day 45, n (%)	51 (68.0)	57 (75.0)	
Age Group (years)			0.7320
Day 15			
18 - 24, n / N (%)	18/25 (72.0)	14/17 (82.4)	
25 - 45, n / N (%)	36/50 (72.0)	39/59 (66.1)	
Day 45			
18 - 24, n / N (%)	15/25 (60.0)	11/17 (64.7)	
25 - 45, n / N (%)	36/50 (72.0)	46/59 (78.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-int.sas:t-sf36-re-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.2235
Day 15			
<28, n / N (%)	17/22 (77.3)	19/30 (63.3)	
>=28, n / N (%)	37/53 (69.8)	34/46 (73.9)	
Day 45			
<28, n / N (%)	16/22 (72.7)	22/30 (73.3)	
>=28, n / N (%)	35/53 (66.0)	35/46 (76.1)	
Race Group (Black or African American, White)			0.7207
Day 15			
Black or African American, n / N (%)	19/32 (59.4)	20/31 (64.5)	
White, n / N (%)	32/40 (80.0)	32/44 (72.7)	
Day 45			
Black or African American, n / N (%)	22/32 (68.8)	23/31 (74.2)	
White, n / N (%)	26/40 (65.0)	33/44 (75.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-int.sas:t-sf36-re-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.0594
Day 15			
Yes, n / N (%)	8/13 (61.5)	13/16 (81.3)	
No, n / N (%)	46/62 (74.2)	40/60 (66.7)	
Day 45			
Yes, n / N (%)	7/13 (53.8)	13/16 (81.3)	
No, n / N (%)	44/62 (71.0)	44/60 (73.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-int.sas:t-sf36-re-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.3564(a) 0.8752(b) 0.2373(c)
Day 15			
<=24.9, n / N (%)	17/21 (81.0)	10/13 (76.9)	
25-29.9, n / N (%)	14/20 (70.0)	13/21 (61.9)	
>=30, n / N (%)	23/34 (67.6)	30/42 (71.4)	
Day 45			
<=24.9, n / N (%)	12/21 (57.1)	9/13 (69.2)	
25-29.9, n / N (%)	16/20 (80.0)	14/21 (66.7)	
>=30, n / N (%)	23/34 (67.6)	34/42 (81.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-int.sas:t-sf36-re-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.4171
Day 15			
3rd Trimester, n / N (%)	20/32 (62.5)	22/32 (68.8)	
Postpartum, n / N (%)	34/43 (79.1)	31/44 (70.5)	
Day 45			
3rd Trimester, n / N (%)	21/32 (65.6)	24/32 (75.0)	
Postpartum, n / N (%)	30/43 (69.8)	33/44 (75.0)	
Family History of PPD			0.9079
Day 15			
Yes, n / N (%)	6/10 (60.0)	7/10 (70.0)	
No/Unknown, n / N (%)	48/65 (73.8)	46/66 (69.7)	
Day 45			
Yes, n / N (%)	8/10 (80.0)	7/10 (70.0)	
No/Unknown, n / N (%)	43/65 (66.2)	50/66 (75.8)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-int.sas:t-sf36-re-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.4190
Day 15			
1st Episode, n / N (%)	44/59 (74.6)	46/66 (69.7)	
Recurrent Episode, n / N (%)	10/16 (62.5)	7/10 (70.0)	
Day 45			
1st Episode, n / N (%)	41/59 (69.5)	49/66 (74.2)	
Recurrent Episode, n / N (%)	10/16 (62.5)	8/10 (80.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	7/8 (87.5)	5/10 (50.0)	
>=20, n / N (%)	47/67 (70.1)	48/66 (72.7)	
Day 45			
<20, n / N (%)	6/8 (75.0)	6/10 (60.0)	
>=20, n / N (%)	45/67 (67.2)	51/66 (77.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-int.sas:t-sf36-re-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

2.9.2.1 .2 .2 Subgruppenanalysen

2.9.2.1 .2 .2 .1 Alter

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 15		
Number of subjects with a response, n (%) [2]	18 (72.0)	14 (82.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.033
95% CI for the RR		(0.739, 1.444)
p-value for RR		0.8495
Day 45		
Number of subjects with a response, n (%) [2]	15 (60.0)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.082
95% CI for the RR		(0.691, 1.692)
p-value for RR		0.7311

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 15		
Number of subjects with a response, n (%) [2]	36 (72.0)	39 (66.1)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.930
95% CI for the RR		(0.727, 1.189)
p-value for RR		0.5620
Day 45		
Number of subjects with a response, n (%) [2]	36 (72.0)	46 (78.0)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.087
95% CI for the RR		(0.874, 1.352)
p-value for RR		0.4514

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.9.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 15		
Number of subjects with a response, n (%) [2]	17 (77.3)	19 (63.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.794
95% CI for the RR		(0.559, 1.128)
p-value for RR		0.1987
Day 45		
Number of subjects with a response, n (%) [2]	16 (72.7)	22 (73.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.977
95% CI for the RR		(0.692, 1.380)
p-value for RR		0.8960

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 15		
Number of subjects with a response, n (%) [2]	37 (69.8)	34 (73.9)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.067
95% CI for the RR		(0.834, 1.365)
p-value for RR		0.6043
Day 45		
Number of subjects with a response, n (%) [2]	35 (66.0)	35 (76.1)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.161
95% CI for the RR		(0.904, 1.493)
p-value for RR		0.2425

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.9.2.1 .2 .2 .3 Abstammung

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 15		
Number of subjects with a response, n (%) [2]	19 (59.4)	20 (64.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.090
95% CI for the RR		(0.741, 1.606)
p-value for RR		0.6610
Day 45		
Number of subjects with a response, n (%) [2]	22 (68.8)	23 (74.2)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.083
95% CI for the RR		(0.790, 1.486)
p-value for RR		0.6209

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 15		
Number of subjects with a response, n (%) [2]	32 (80.0)	32 (72.7)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.901
95% CI for the RR		(0.715, 1.135)
p-value for RR		0.3773
Day 45		
Number of subjects with a response, n (%) [2]	26 (65.0)	33 (75.0)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.144
95% CI for the RR		(0.863, 1.515)
p-value for RR		0.3492

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.9.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 15		
Number of subjects with a response, n (%) [2]	8 (61.5)	13 (81.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.258
95% CI for the RR		(0.785, 2.016)
p-value for RR		0.3404
Day 45		
Number of subjects with a response, n (%) [2]	7 (53.8)	13 (81.3)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.447
95% CI for the RR		(0.841, 2.490)
p-value for RR		0.1816

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 15		
Number of subjects with a response, n (%) [2]	46 (74.2)	40 (66.7)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.896
95% CI for the RR		(0.722, 1.111)
p-value for RR		0.3174
Day 45		
Number of subjects with a response, n (%) [2]	44 (71.0)	44 (73.3)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.008
95% CI for the RR		(0.828, 1.227)
p-value for RR		0.9371

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.9.2.1 .2 .2 .5 BMI

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 15		
Number of subjects with a response, n (%) [2]	17 (81.0)	10 (76.9)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.976
95% CI for the RR		(0.685, 1.392)
p-value for RR		0.8937
Day 45		
Number of subjects with a response, n (%) [2]	12 (57.1)	9 (69.2)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.245
95% CI for the RR		(0.757, 2.045)
p-value for RR		0.3881

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 15		
Number of subjects with a response, n (%) [2]	14 (70.0)	13 (61.9)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.880
95% CI for the RR		(0.565, 1.371)
p-value for RR		0.5725
Day 45		
Number of subjects with a response, n (%) [2]	16 (80.0)	14 (66.7)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.829
95% CI for the RR		(0.567, 1.212)
p-value for RR		0.3336

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 15		
Number of subjects with a response, n (%) [2]	23 (67.6)	30 (71.4)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.056
95% CI for the RR		(0.783, 1.423)
p-value for RR		0.7214
Day 45		
Number of subjects with a response, n (%) [2]	23 (67.6)	34 (81.0)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.197
95% CI for the RR		(0.908, 1.577)
p-value for RR		0.2028

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.9.2.1 .2 .2 .6 Beginn der PPD

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 15		
Number of subjects with a response, n (%) [2]	20 (62.5)	22 (68.8)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.102
95% CI for the RR		(0.773, 1.571)
p-value for RR		0.5897
Day 45		
Number of subjects with a response, n (%) [2]	21 (65.6)	24 (75.0)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.145
95% CI for the RR		(0.835, 1.572)
p-value for RR		0.4008

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 15		
Number of subjects with a response, n (%) [2]	34 (79.1)	31 (70.5)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.887
95% CI for the RR		(0.700, 1.124)
p-value for RR		0.3207
Day 45		
Number of subjects with a response, n (%) [2]	30 (69.8)	33 (75.0)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.070
95% CI for the RR		(0.823, 1.391)
p-value for RR		0.6116

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.9.2.1 .2 .2 .7 PPD in der Familie

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 15		
Number of subjects with a response, n (%) [2]	6 (60.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.270
95% CI for the RR		(0.666, 2.423)
p-value for RR		0.4681
Day 45		
Number of subjects with a response, n (%) [2]	8 (80.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.953
95% CI for the RR		(0.531, 1.709)
p-value for RR		0.8706

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 15		
Number of subjects with a response, n (%) [2]	48 (73.8)	46 (69.7)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.938
95% CI for the RR		(0.757, 1.163)
p-value for RR		0.5586
Day 45		
Number of subjects with a response, n (%) [2]	43 (66.2)	50 (75.8)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.138
95% CI for the RR		(0.913, 1.418)
p-value for RR		0.2491

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.9.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 15		
Number of subjects with a response, n (%) [2]	44 (74.6)	46 (69.7)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.936
95% CI for the RR		(0.754, 1.162)
p-value for RR		0.5496
Day 45		
Number of subjects with a response, n (%) [2]	41 (69.5)	49 (74.2)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.070
95% CI for the RR		(0.861, 1.330)
p-value for RR		0.5419

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 15		
Number of subjects with a response, n (%) [2]	10 (62.5)	7 (70.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.056
95% CI for the RR		(0.632, 1.764)
p-value for RR		0.8342
Day 45		
Number of subjects with a response, n (%) [2]	10 (62.5)	8 (80.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.207
95% CI for the RR		(0.695, 2.096)
p-value for RR		0.5034

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Role-Emotional subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Role-Emotional subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

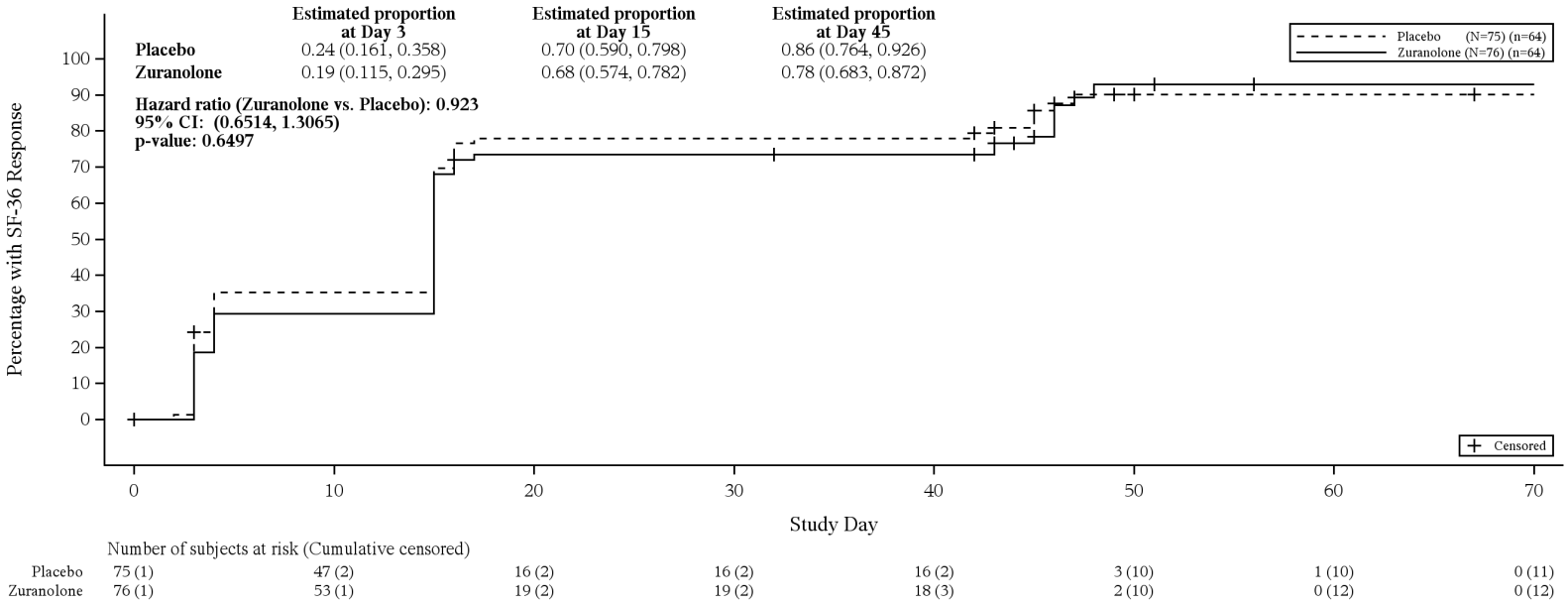
Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-201-by.sas:t-sf36-re-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.9.2.2 TTE-Analysen

2.9.2.2 .1 ITT-Population

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-ovr.sas:f-sf36-re-resp15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	64 (85.3)	64 (84.2)
Time to first SF-36 Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 4.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (15.0 , 45.0)	43.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.923
95% CI for the HR		(0.6514 , 1.3065)
p-value for the HR		0.6497

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-ovr.sas:t-sf36-re-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.9.2.2 .2 Subgruppen

2.9.2.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	64 (85.3)	64 (84.2)	
Age Group (years)			
18 - 24, n / N (%)	20/25 (80.0)	15/17 (88.2)	0.2877
25 - 45, n / N (%)	44/50 (88.0)	49/59 (83.1)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	19/22 (86.4)	24/30 (80.0)	0.7878
>=28, n / N (%)	45/53 (84.9)	40/46 (87.0)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	28/32 (87.5)	27/31 (87.1)	0.8805
White, n / N (%)	33/40 (82.5)	36/44 (81.8)	
Antidepressant Use at Baseline			
Yes, n / N (%)	10/13 (76.9)	15/16 (93.8)	0.0560
No, n / N (%)	54/62 (87.1)	49/60 (81.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-int.sas:t-sf36-re-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	18/21 (85.7)	12/13 (92.3)	0.9206(a)
25-29.9, n / N (%)	16/20 (80.0)	14/21 (66.7)	0.7064(b)
>=30, n / N (%)	30/34 (88.2)	38/42 (90.5)	0.6159(c)
Onset of PPD			
3rd Trimester, n / N (%)	26/32 (81.3)	27/32 (84.4)	0.3286
Postpartum, n / N (%)	38/43 (88.4)	37/44 (84.1)	
Family History of PPD			
Yes, n / N (%)	9/10 (90.0)	9/10 (90.0)	0.4195
No/Unknown, n / N (%)	55/65 (84.6)	55/66 (83.3)	
History of PPD			
1st Episode, n / N (%)	51/59 (86.4)	55/66 (83.3)	0.6906
Recurrent Episode, n / N (%)	13/16 (81.3)	9/10 (90.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	7/8 (87.5)	7/10 (70.0)	NA
>=20, n / N (%)	57/67 (85.1)	57/66 (86.4)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-int.sas:t-sf36-re-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.9.2.2 .2 .2 Subgruppenanalysen

2.9.2.2 .2 .2 .1 Alter

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	20 (80.0)	15 (88.2)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	3.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 17.0)	15.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	42.0 (15.0, NE)	15.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.283
95% CI for the HR		(0.6330 , 2.6024)
p-value for the HR		0.4890

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	44 (88.0)	49 (83.1)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (15.0 , 45.0)	45.0 (15.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.812
95% CI for the HR		(0.5374 , 1.2272)
p-value for the HR		0.3230

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.9.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	19 (86.4)	24 (80.0)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (4.0 , 16.0)
75th percentile - Q3 (95% CI)	15.0 (15.0, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.987
95% CI for the HR		(0.5374 , 1.8131)
p-value for the HR		0.9666

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	45 (84.9)	40 (87.0)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (15.0 , 46.0)	17.0 (15.0 , 48.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.902
95% CI for the HR		(0.5864 , 1.3877)
p-value for the HR		0.6391

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.9.2.2 .2 .2 .3 Abstammung

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	28 (87.5)	27 (87.1)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	43.0 (15.0 , 47.0)	45.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.873
95% CI for the HR		(0.5140 , 1.4813)
p-value for the HR		0.6136

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	33 (82.5)	36 (81.8)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	3.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (15.0, NE)	43.0 (15.0 , 48.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.970
95% CI for the HR		(0.6005 , 1.5659)
p-value for the HR		0.9000

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.9.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	10 (76.9)	15 (93.8)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 16.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	16.0 (3.0 , 45.0)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	15.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.439
95% CI for the HR		(0.5874 , 3.5252)
p-value for the HR		0.4260

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	54 (87.1)	49 (81.7)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 4.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (15.0 , 45.0)	45.0 (15.0 , 48.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.773
95% CI for the HR		(0.5239 , 1.1395)
p-value for the HR		0.1931

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.9.2.2 .2 .2 .5 BMI

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	18 (85.7)	12 (92.3)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	9.5 (3.0 , 15.0)	15.0 (3.0 , 17.0)
75th percentile - Q3 (95% CI)	15.0 (15.0, NE)	17.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.896
95% CI for the HR		(0.4165 , 1.9265)
p-value for the HR		0.7781

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	16 (80.0)	14 (66.7)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	9.5 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 45.0)	15.0 (15.0, NE)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.832
95% CI for the HR		(0.4054 , 1.7092)
p-value for the HR		0.6173

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

Page: 3 of 3

BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	30 (88.2)	38 (90.5)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (15.0 , 46.0)	16.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.019
95% CI for the HR		(0.6278 , 1.6542)
p-value for the HR		0.9390

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.9.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	26 (81.3)	27 (84.4)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	3.5 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (4.0 , 16.0)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	29.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.082
95% CI for the HR		(0.6269 , 1.8689)
p-value for the HR		0.7763

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	38 (88.4)	37 (84.1)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	16.0 (15.0 , 45.0)	45.0 (15.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.786
95% CI for the HR		(0.4982 , 1.2410)
p-value for the HR		0.3018

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.9.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	9 (90.0)	9 (90.0)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 16.0)	3.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.5 (3.0 , 45.0)	15.0 (3.0 , 47.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	47.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.469
95% CI for the HR		(0.4317 , 5.0023)
p-value for the HR		0.5380

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	55 (84.6)	55 (83.3)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (15.0 , 45.0)	43.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.863
95% CI for the HR		(0.5921 , 1.2573)
p-value for the HR		0.4424

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.9.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	51 (86.4)	55 (83.3)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (15.0 , 45.0)	43.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.884
95% CI for the HR		(0.6018 , 1.2972)
p-value for the HR		0.5274

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-resp15-tte-201-by.sas:t-sf36-re-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	13 (81.3)	9 (90.0)
Time to first Role-Emotional Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 16.0)	15.0 (3.0 , 47.0)
75th percentile - Q3 (95% CI)	16.0 (15.0, NE)	47.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.987
95% CI for the HR		(0.3525 , 2.7655)
p-value for the HR		0.9807

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

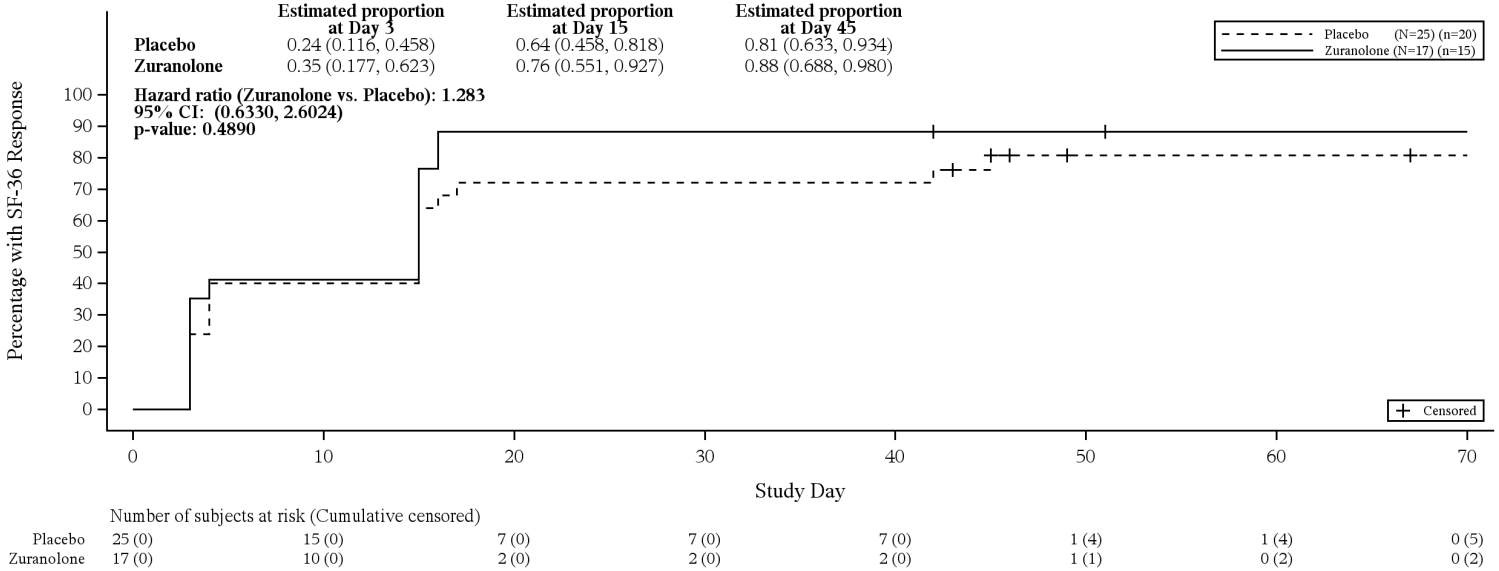
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2.9.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

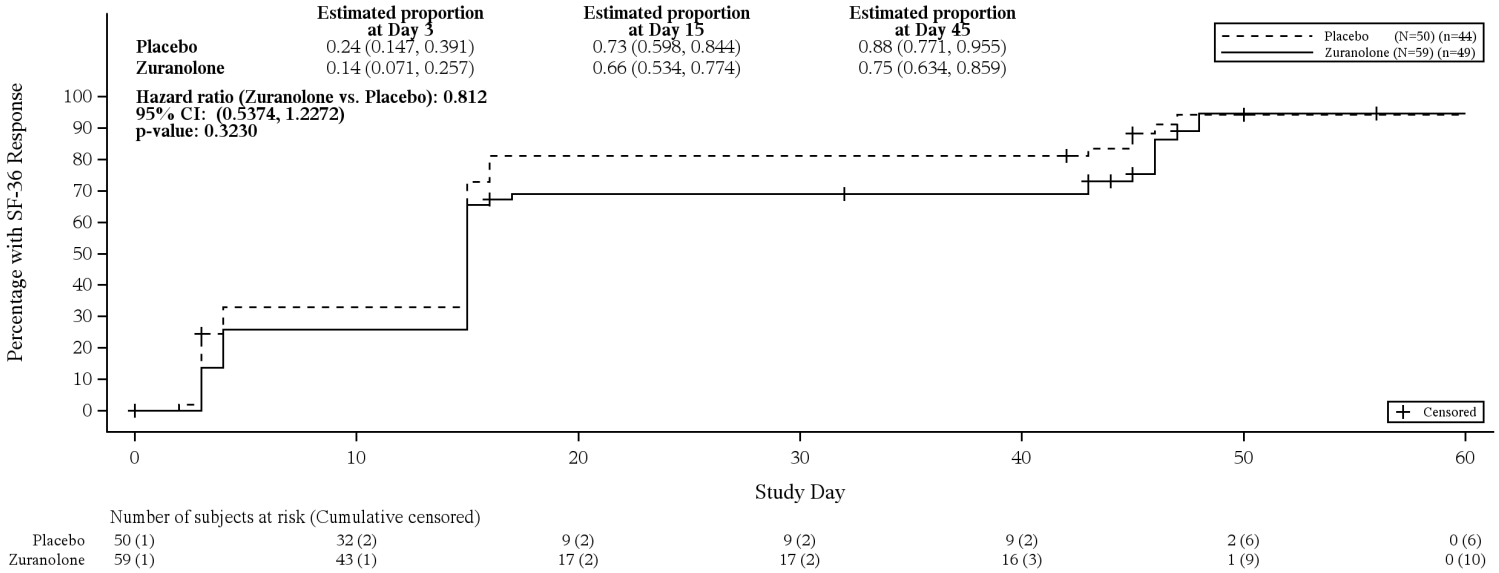
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

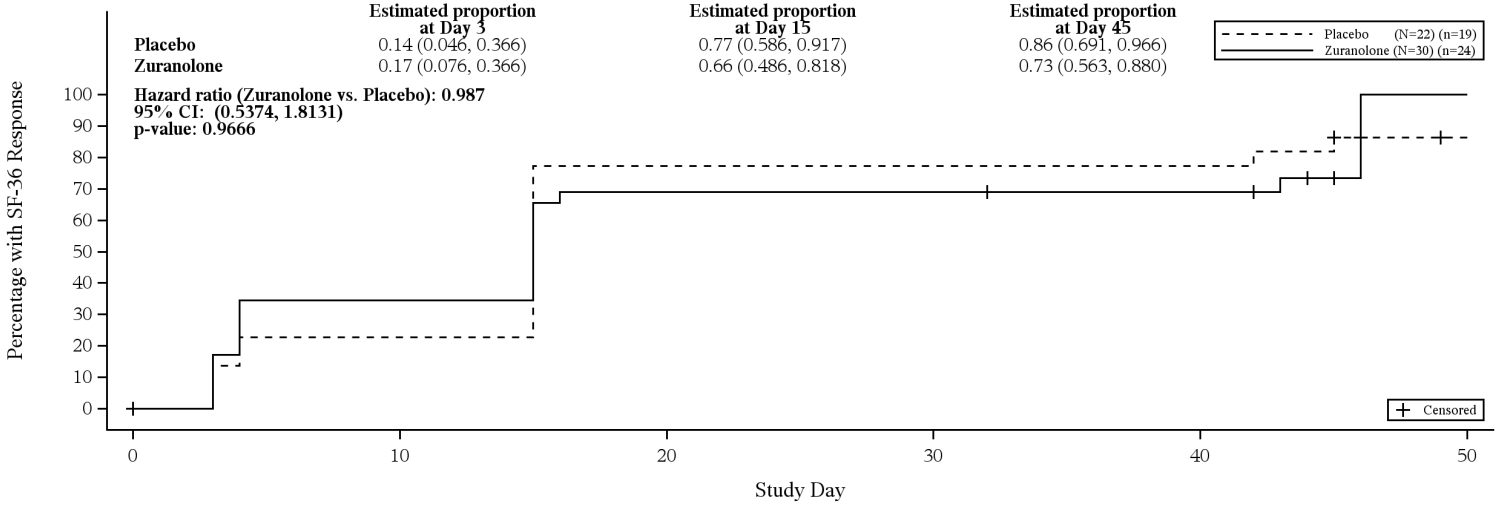
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	17 (0)	5 (0)	5 (0)	5 (0)	0 (3)
Zuranolone	30 (1)	19 (1)	9 (1)	9 (1)	8 (2)	0 (6)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

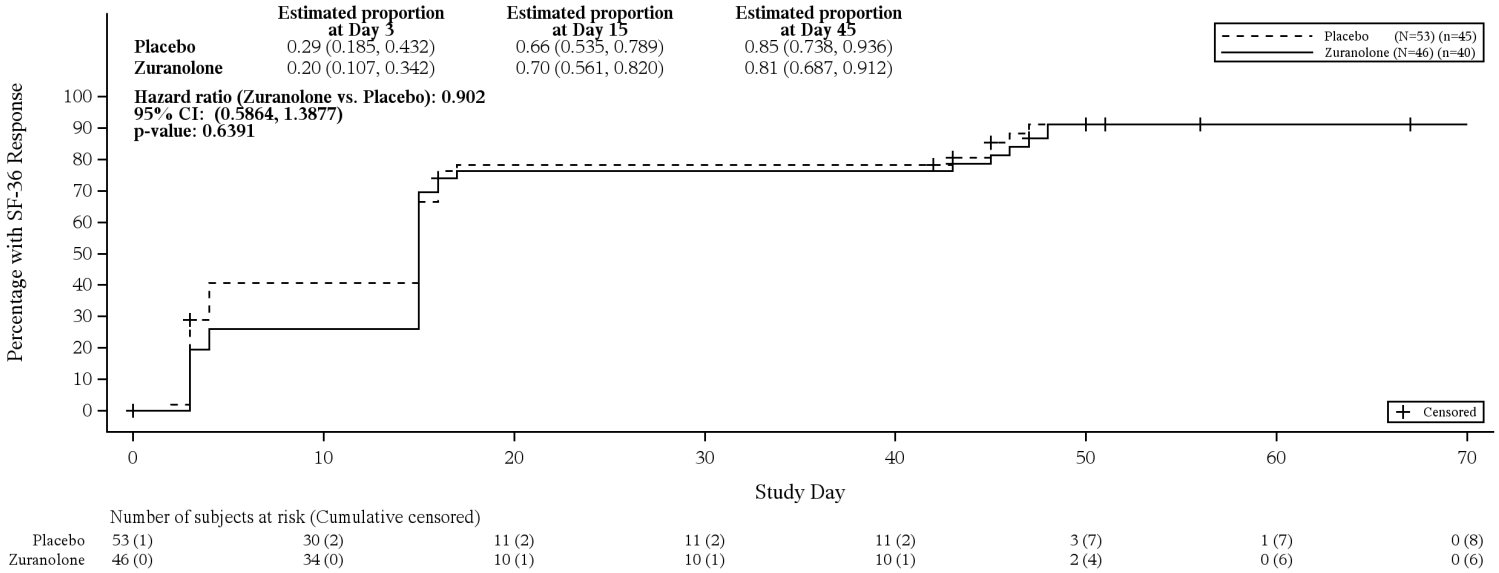
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

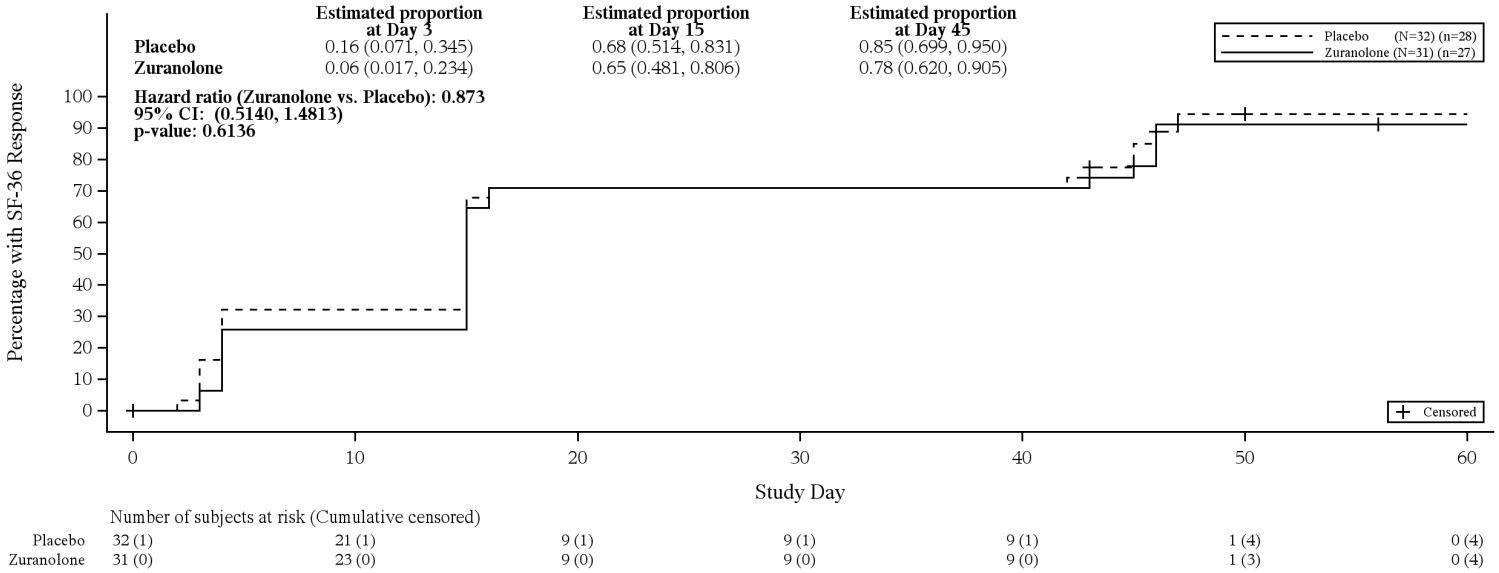
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

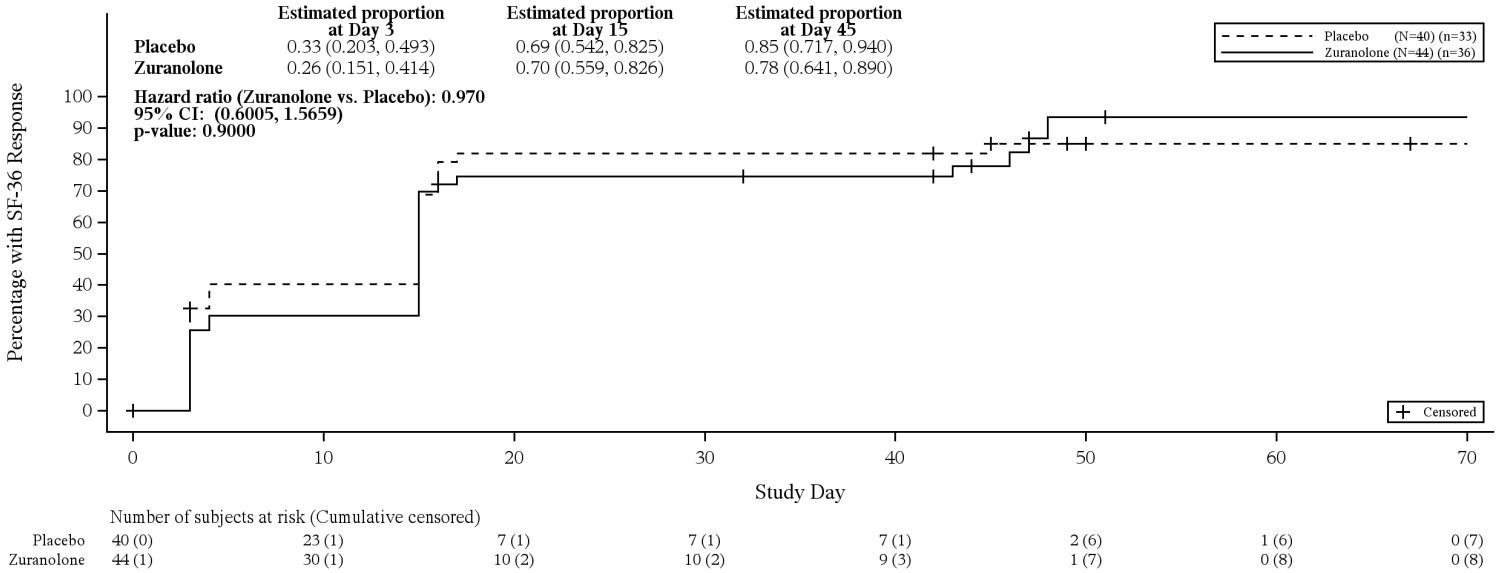
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

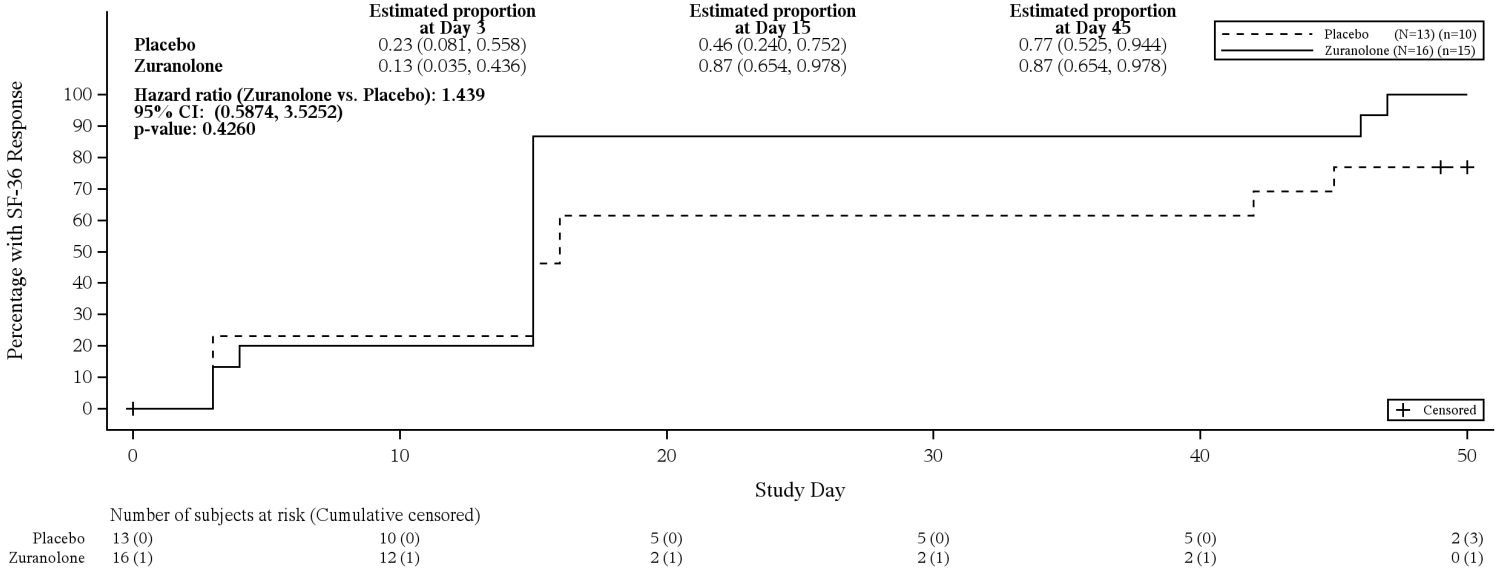
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	13 (0)	10 (0)	5 (0)	5 (0)	5 (0)	2 (3)
Zuranolone	16 (1)	12 (1)	2 (1)	2 (1)	2 (1)	0 (1)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

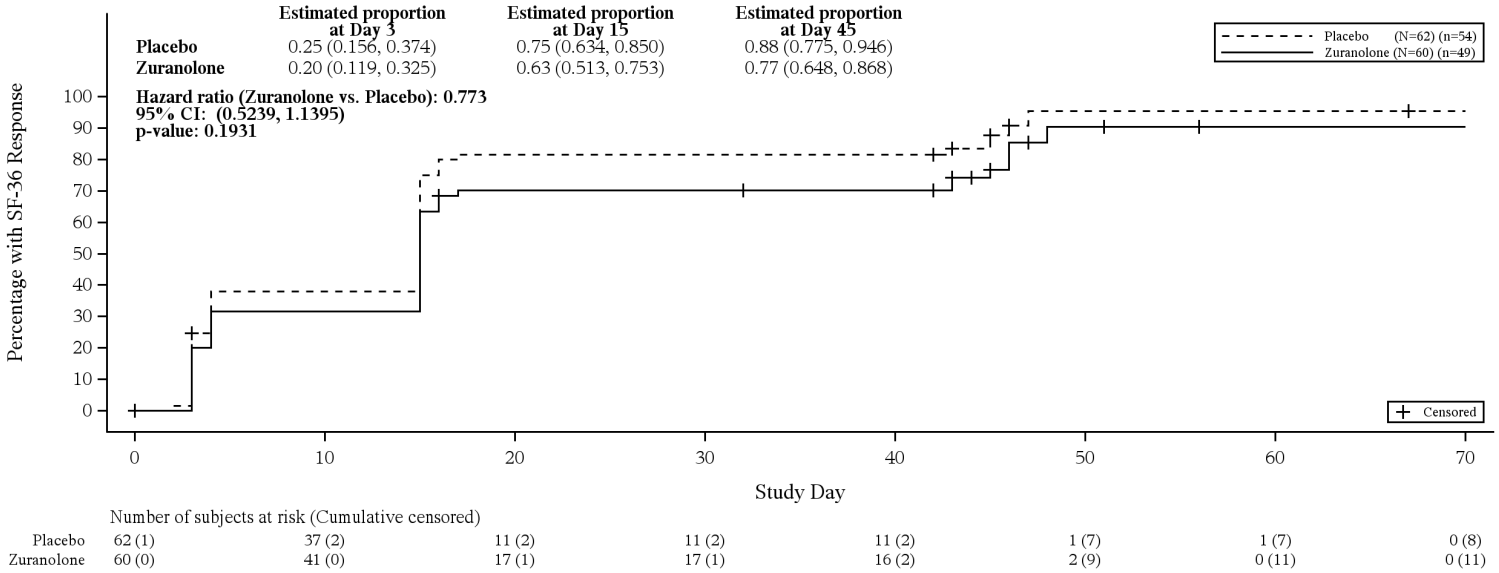
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

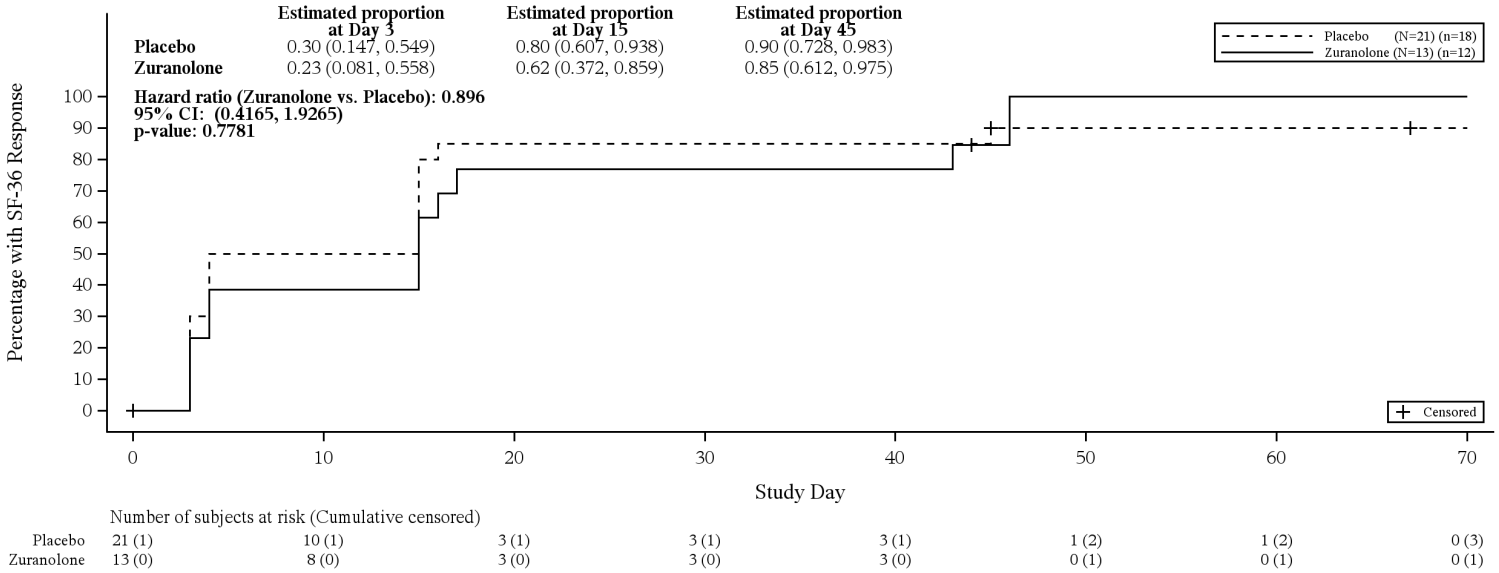
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

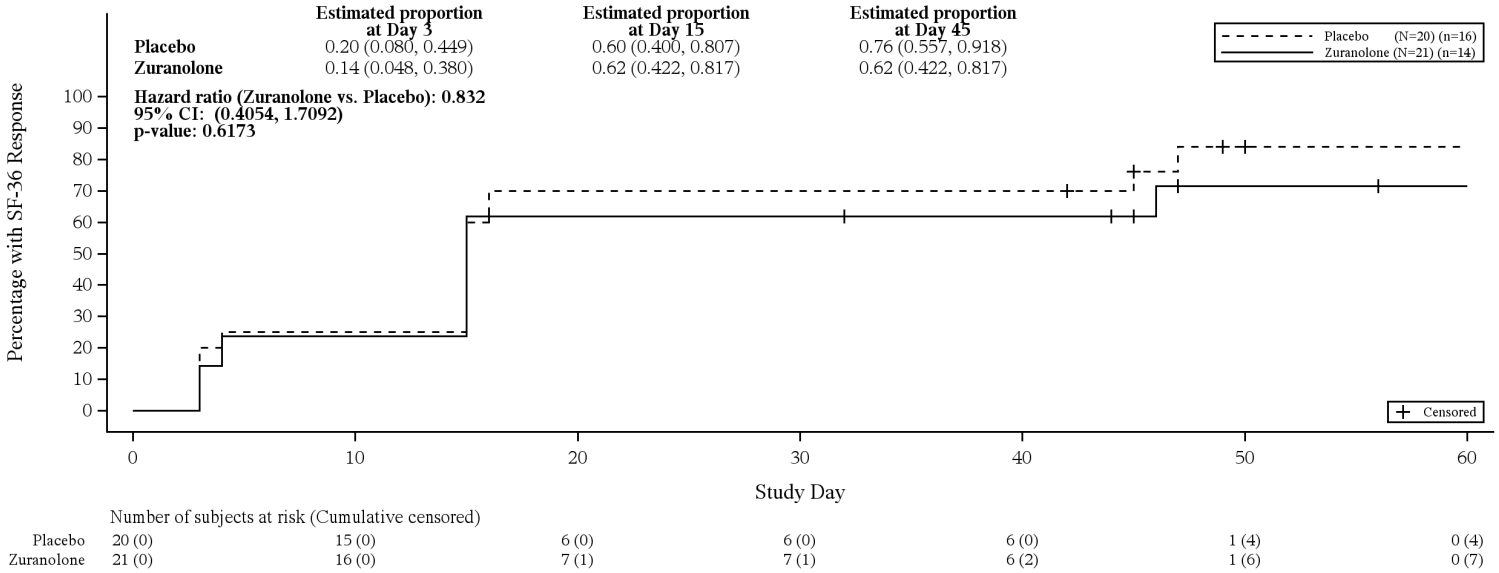
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

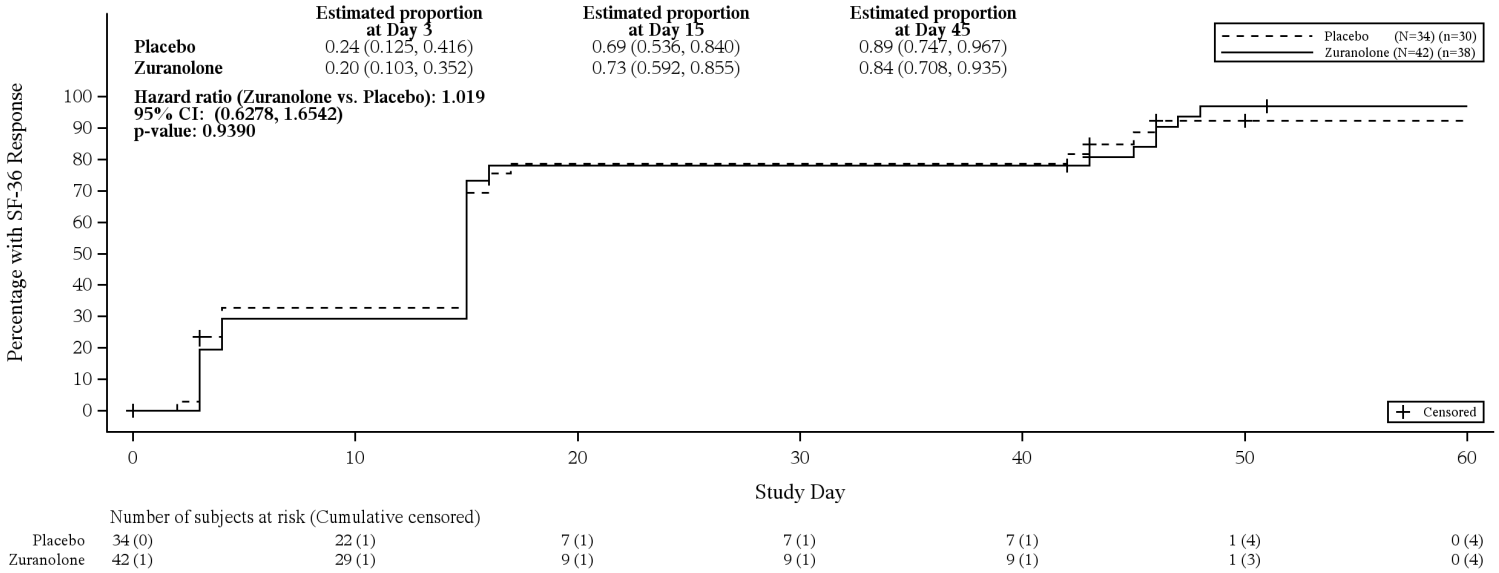
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

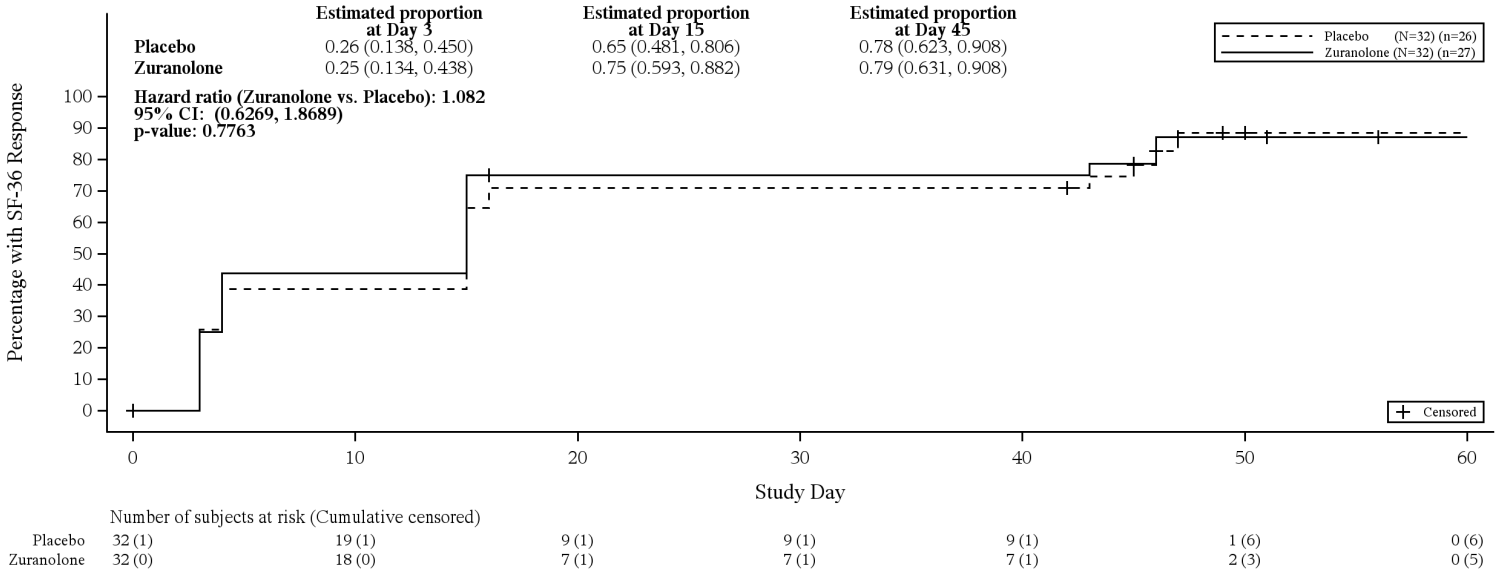
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

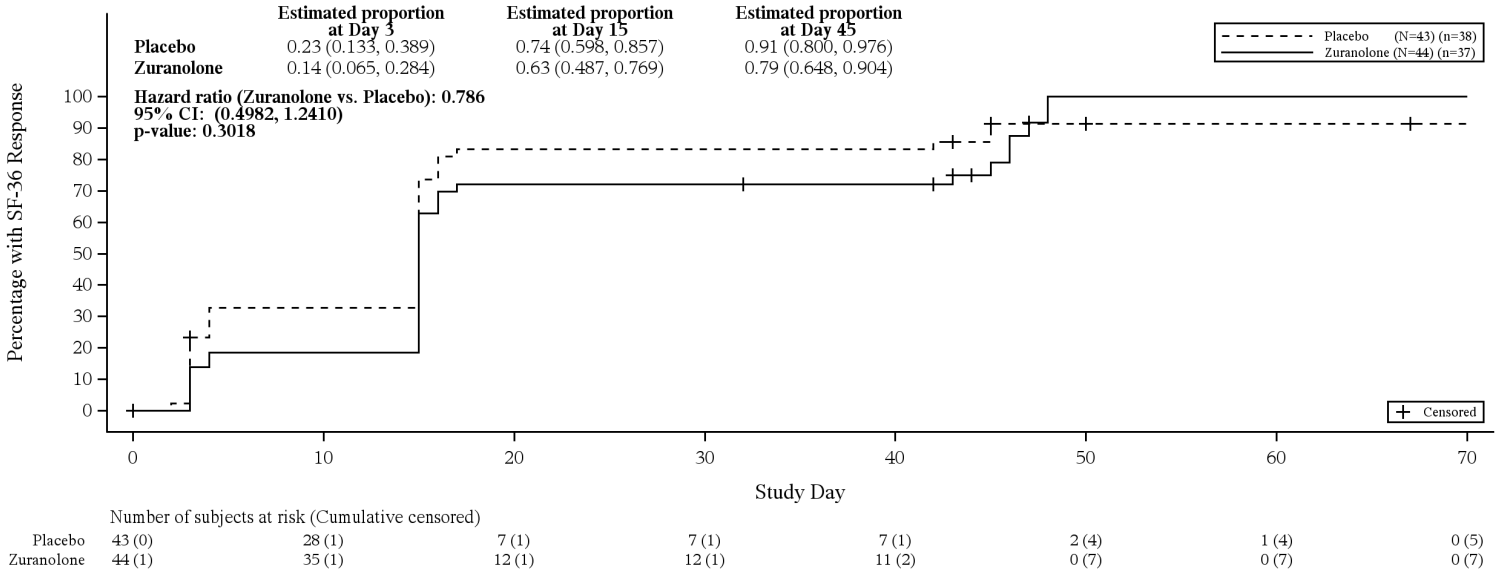
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

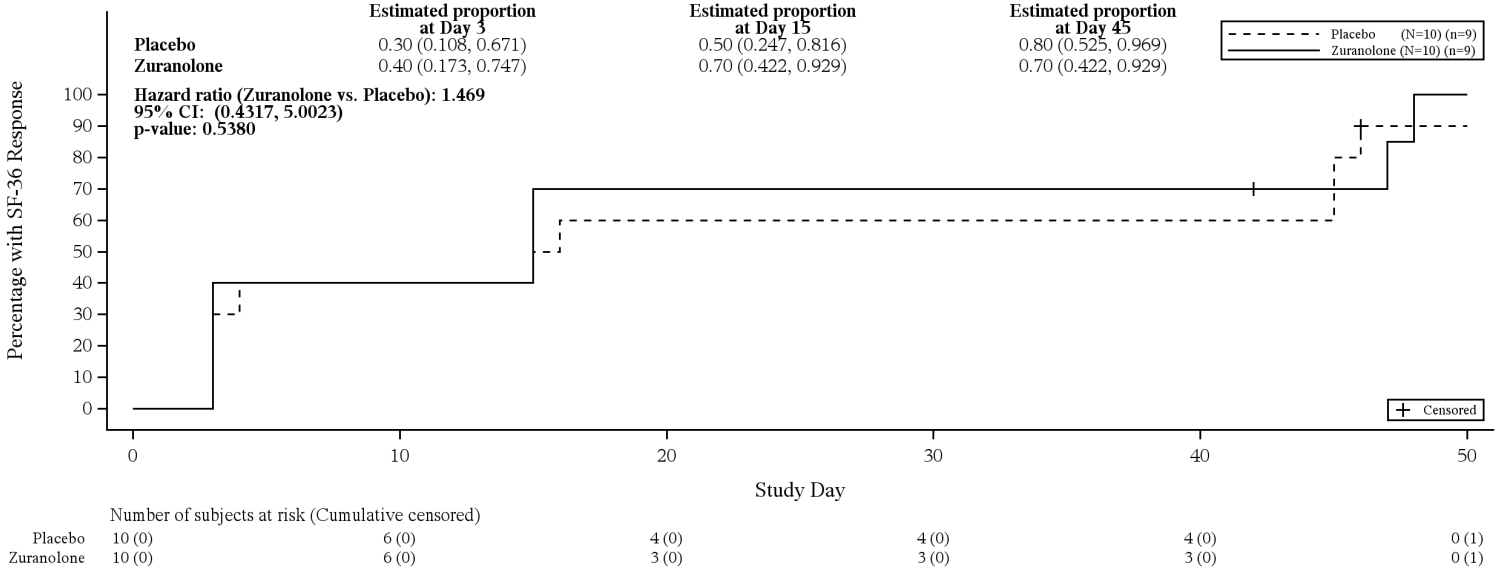
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

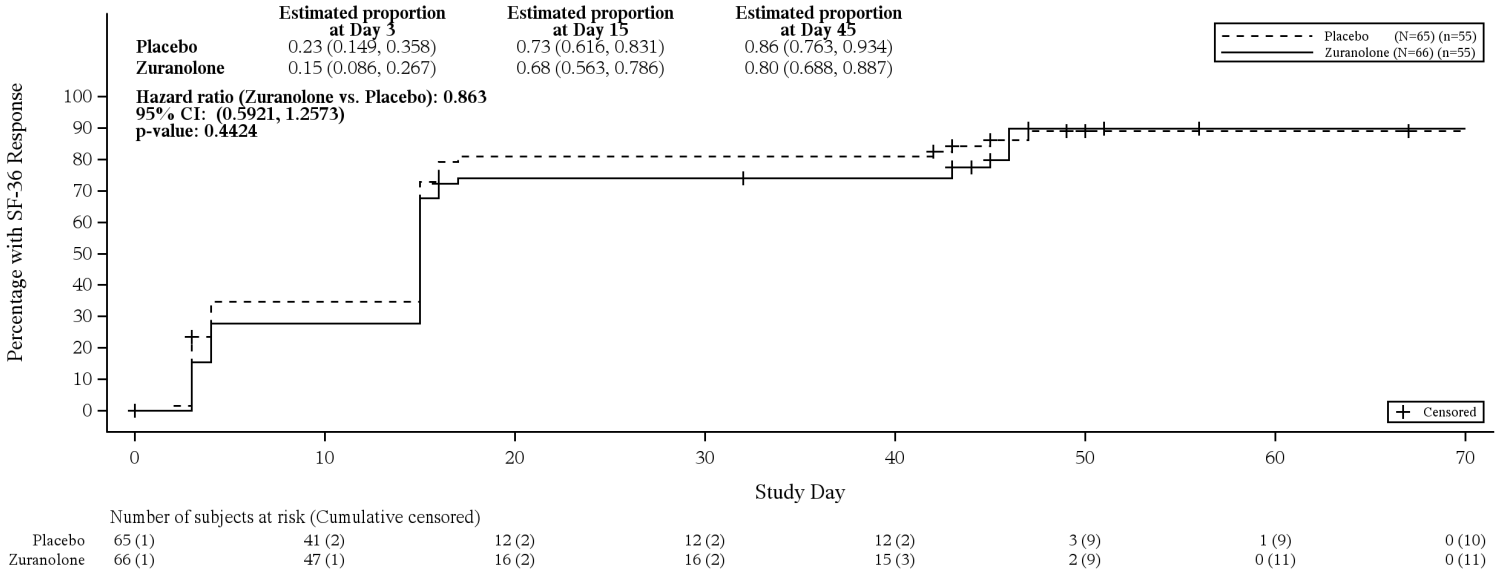
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

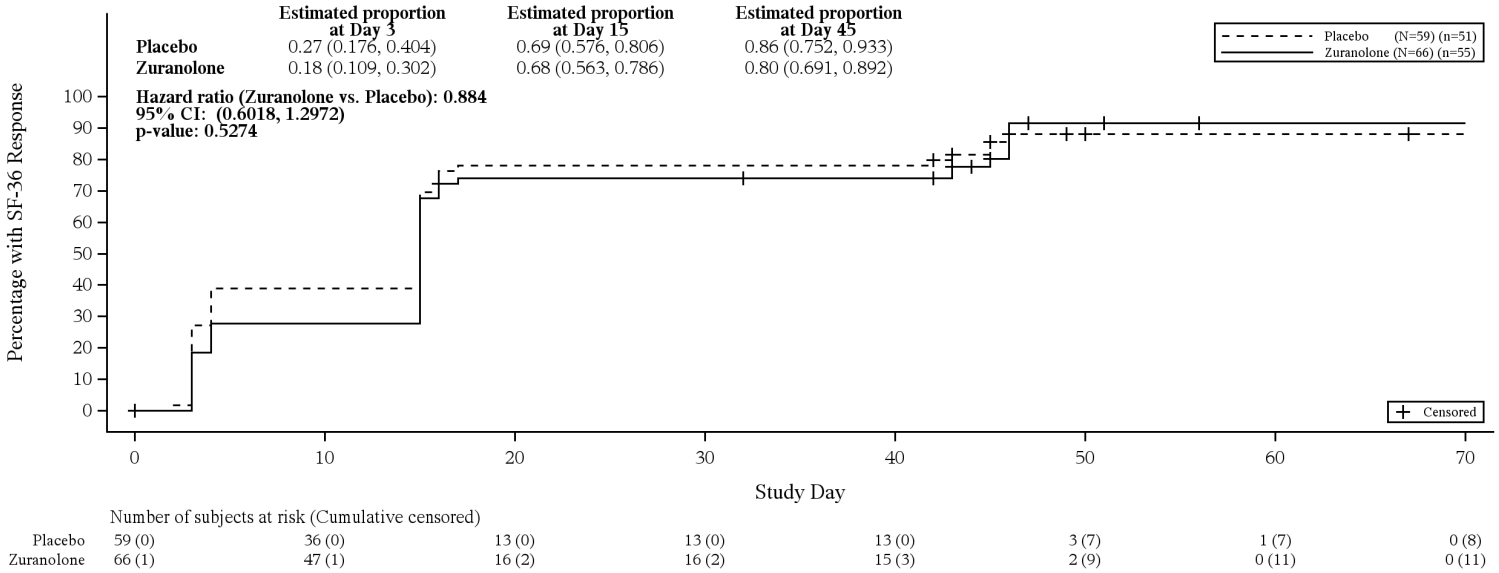
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

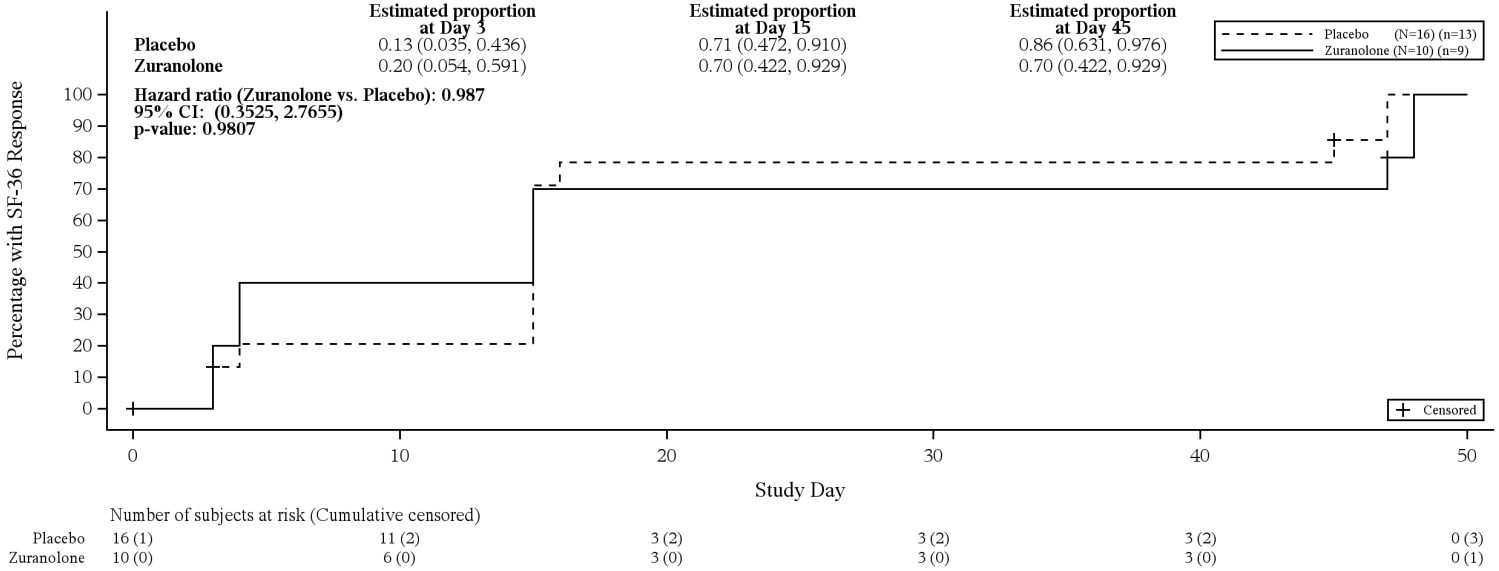
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Number of subjects at risk (Cumulative censored)

Placebo	16 (1)	11 (2)	3 (2)	3 (2)	3 (2)	0 (3)
Zuranolone	10 (0)	6 (0)	3 (0)	3 (0)	3 (0)	0 (1)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-re-resp15-tte-201-by.sas:f-sf36-re-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

2.9.3 Verschlechterung

2.9.3.1 Responder-Analysen

2.9.3.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with worsening, n (%) [2]	5 (6.7)	5 (6.6)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.99
95% CI for the RR		(0.298, 3.269)
p-value for RR		0.9827
OR - Odds Ratio (Zuranolone vs. Placebo)		0.99
95% CI for the OR		(0.273, 3.556)
p-value for OR		0.9827
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.080, 0.078)
p-value for ARR		0.9827

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Role-Emotional subscale score worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-re-wors15-201-ovr.sas:t-sf36-re-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	5 (6.7)	1 (1.3)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.20
95% CI for the RR		(0.024, 1.650)
p-value for RR		0.1342
OR - Odds Ratio (Zuranolone vs. Placebo)		0.19
95% CI for the OR		(0.021, 1.637)
p-value for OR		0.1298
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.05
95% CI for the ARR		(-0.116, 0.008)
p-value for ARR		0.0907

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing SF-36 Role-Emotional subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Role-Emotional subscale score worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-re-wors15-201-ovr.sas:t-sf36-re-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.9.3.1 .2 Subgruppen

2.9.3.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	5 (6.7)	5 (6.6)	
Number of subjects with response at Day 45, n (%)	5 (6.7)	1 (1.3)	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	2/25 (8.0)	1/17 (5.9)	
25 - 45, n / N (%)	3/50 (6.0)	4/59 (6.8)	
Day 45			
18 - 24, n / N (%)	4/25 (16.0)	0/17	
25 - 45, n / N (%)	1/50 (2.0)	1/59 (1.7)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-wors15-201-int.sas:t-sf36-re-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	0/22	1/30 (3.3)	
>=28, n / N (%)	5/53 (9.4)	4/46 (8.7)	
Day 45			
<28, n / N (%)	1/22 (4.5)	1/30 (3.3)	
>=28, n / N (%)	4/53 (7.5)	0/46	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	3/32 (9.4)	1/31 (3.2)	
White, n / N (%)	2/40 (5.0)	4/44 (9.1)	
Day 45			
Black or African American, n / N (%)	3/32 (9.4)	0/31	
White, n / N (%)	2/40 (5.0)	1/44 (2.3)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-wors15-201-int.sas:t-sf36-re-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	5/62 (8.1)	5/60 (8.3)	
Day 45			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	5/62 (8.1)	1/60 (1.7)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-wors15-201-int.sas:t-sf36-re-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 4 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	1/21 (4.8)	0/13	
25-29.9, n / N (%)	1/20 (5.0)	3/21 (14.3)	
>=30, n / N (%)	3/34 (8.8)	2/42 (4.8)	
Day 45			
<=24.9, n / N (%)	3/21 (14.3)	0/13	
25-29.9, n / N (%)	0/20	1/21 (4.8)	
>=30, n / N (%)	2/34 (5.9)	0/42	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-wors15-201-int.sas:t-sf36-re-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 5 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	2/32 (6.3)	3/32 (9.4)	
Postpartum, n / N (%)	3/43 (7.0)	2/44 (4.5)	
Day 45			
3rd Trimester, n / N (%)	2/32 (6.3)	0/32	
Postpartum, n / N (%)	3/43 (7.0)	1/44 (2.3)	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	5/65 (7.7)	5/66 (7.6)	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	5/65 (7.7)	1/66 (1.5)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-wors15-201-int.sas:t-sf36-re-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Role-Emotional Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	3/59 (5.1)	4/66 (6.1)	
Recurrent Episode, n / N (%)	2/16 (12.5)	1/10 (10.0)	
Day 45			
1st Episode, n / N (%)	3/59 (5.1)	1/66 (1.5)	
Recurrent Episode, n / N (%)	2/16 (12.5)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/8	1/10 (10.0)	
>=20, n / N (%)	5/67 (7.5)	4/66 (6.1)	
Day 45			
<20, n / N (%)	1/8 (12.5)	1/10 (10.0)	
>=20, n / N (%)	4/67 (6.0)	0/66	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-wors15-201-int.sas:t-sf36-re-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

2.9.3.1 .2 .2 Subgruppenanalysen

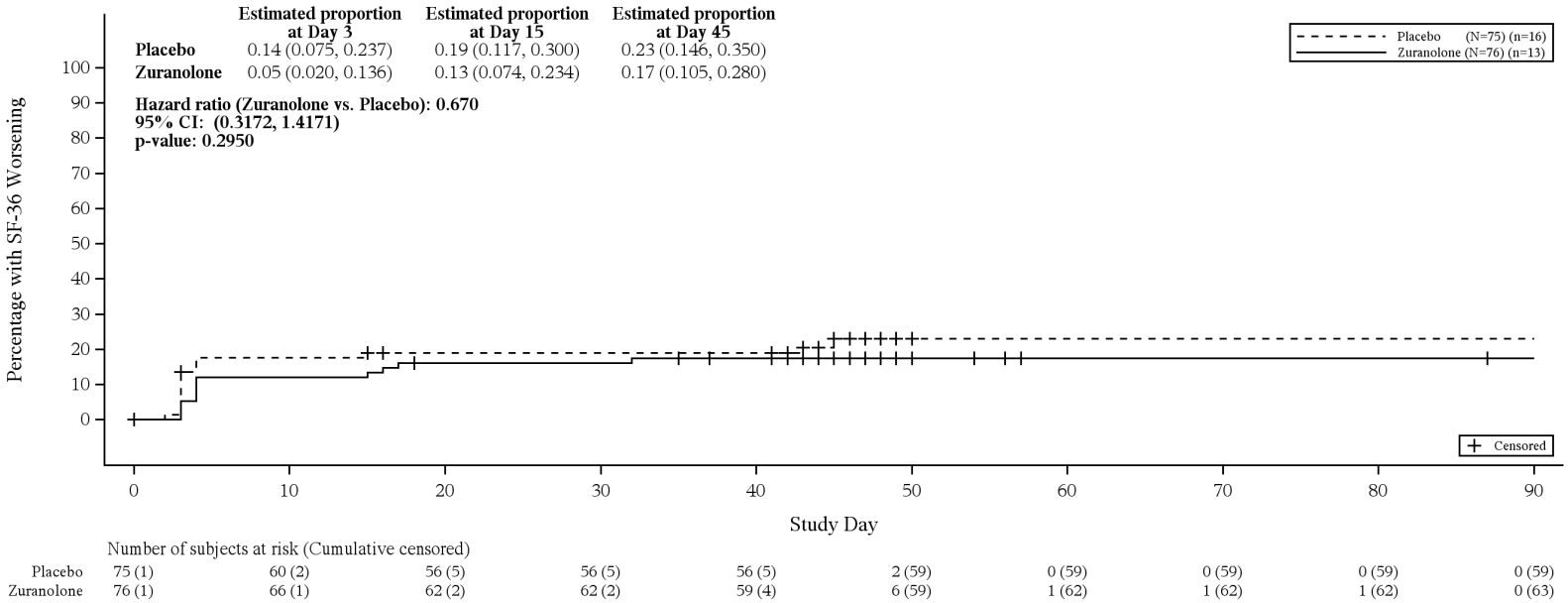
Nicht zutreffend.

2.9.3.2 TTE-Analysen

2.9.3.2 .1 ITT-Population

Kaplan-Meier Plot for First Short-Form 36 (SF-36) Role-Emotional Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-re-wors15-tte-201-ovr.sas:f-sf36-re-wors15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	16 (21.3)	13 (17.1)
Time to first Role-Emotional Subscale worsening (days) [3]		
25th percentile - Q1 (95% CI)	NE (4.0, NE)	NE (17.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.670
95% CI for the HR		(0.3172 , 1.4171)
p-value for the HR		0.2950

NOTE 1: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) worsening. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-re-wors15-tte-201-ovr.sas:t-sf36-re-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.9.3.2 .2 Subgruppen

2.9.3.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	16 (21.3)	13 (17.1)	
Age Group (years)			
18 - 24, n / N (%)	6/25 (24.0)	2/17 (11.8)	0.5360
25 - 45, n / N (%)	10/50 (20.0)	11/59 (18.6)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	3/22 (13.6)	5/30 (16.7)	0.4394
>=28, n / N (%)	13/53 (24.5)	8/46 (17.4)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	9/32 (28.1)	5/31 (16.1)	NA
White, n / N (%)	6/40 (15.0)	8/44 (18.2)	
Antidepressant Use at Baseline			
Yes, n / N (%)	1/13 (7.7)	1/16 (6.3)	0.9303
No, n / N (%)	15/62 (24.2)	12/60 (20.0)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-wors15-tte-201-int.sas:t-sf36-re-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Role-Emotional Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	5/21 (23.8)	2/13 (15.4)	NA(a)
25-29.9, n / N (%)	4/20 (20.0)	4/21 (19.0)	NA(b)
>=30, n / N (%)	7/34 (20.6)	7/42 (16.7)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	8/32 (25.0)	6/32 (18.8)	NA
Postpartum, n / N (%)	8/43 (18.6)	7/44 (15.9)	
Family History of PPD			
Yes, n / N (%)	1/10 (10.0)	0/10	0.9883
No/Unknown, n / N (%)	15/65 (23.1)	13/66 (19.7)	
History of PPD			
1st Episode, n / N (%)	10/59 (16.9)	12/66 (18.2)	0.2166
Recurrent Episode, n / N (%)	6/16 (37.5)	1/10 (10.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	1/8 (12.5)	3/10 (30.0)	NA
>=20, n / N (%)	15/67 (22.4)	10/66 (15.2)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-re-wors15-tte-201-int.sas:t-sf36-re-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.9.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

2.9.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

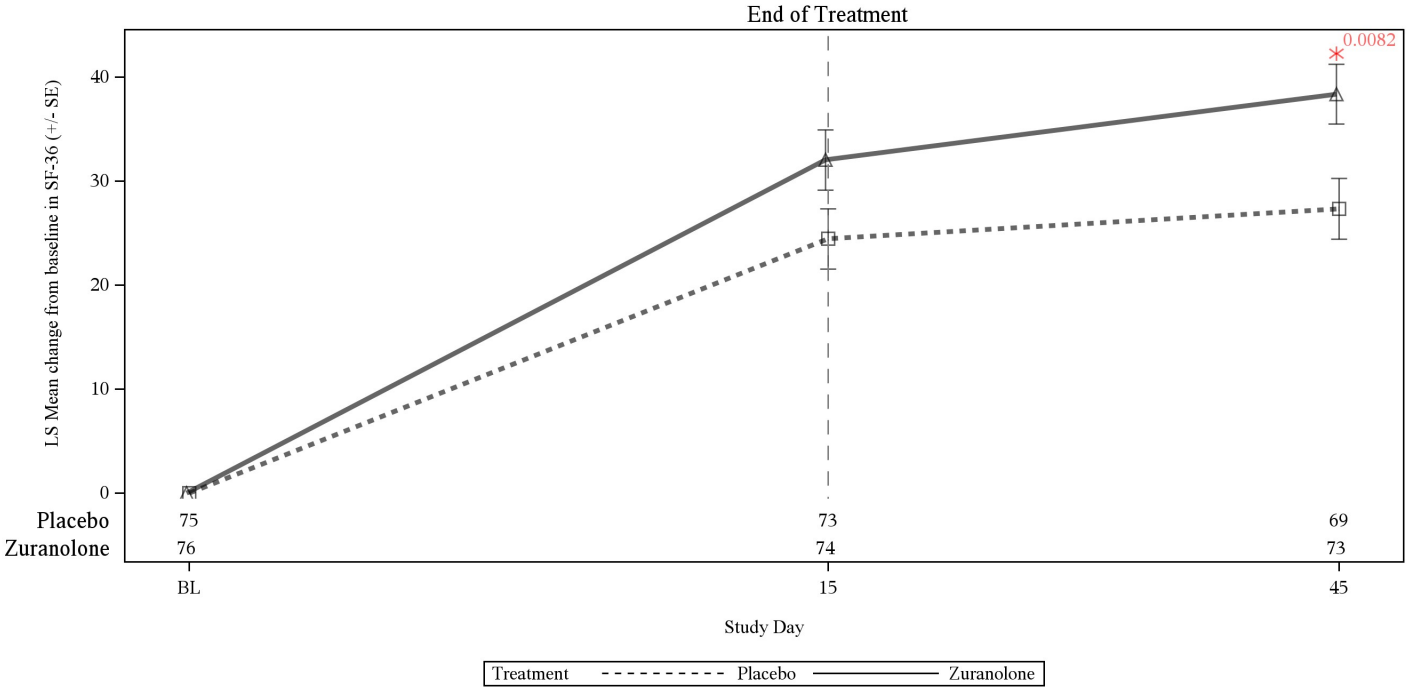
2.10 psychisches Wohlbefinden

2.10.1 MMRM

2.10.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/f-sf36-mh-mmrm-201-ovr.sas:f-sf36-mh-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale: 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	24.44 (2.911)	32.03 (2.886)
95% CI for the LS Mean	18.68, 30.19	26.33, 37.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.60 (4.101)
95% CI for the LS Mean		-0.51, 15.70
p-value		0.0660
Hedges' g (Zuranolone vs. Placebo)		0.304
95% CI for Hedges' g		-0.0212, 0.6292
Day 45		
n	69	73
LS Mean (SE)	27.33 (2.943)	38.36 (2.871)
95% CI for the LS Mean	21.51, 33.15	32.68, 44.03
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.03 (4.115)
95% CI for the LS Mean		2.89, 19.16
p-value		0.0082
Hedges' g (Zuranolone vs. Placebo)		0.448
95% CI for Hedges' g		0.1144, 0.7807

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-ovr.sas:t-sf36-mh-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.10.1.2 Subgruppen

2.10.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.6490
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.6183
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.6582
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.5767
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-int.sas:t-sf36-mh-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.6871(a)
25-29.9	20	21	0.7067(b)
>=30	34	42	0.9376(c)
Onset of PPD			
3rd Trimester	32	32	0.2929
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.3080
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.6958
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-int.sas:t-sf36-mh-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

2.10.1.2 .2 Subgruppenanalysen

2.10.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Day 15		
n	25	17
LS Mean (SE)	23.11 (4.785)	33.03 (5.809)
95% CI for the LS Mean	13.41, 32.80	21.25, 44.80
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.92 (7.538)
95% CI for the LS Mean		-5.36, 25.19
p-value		0.1964
Hedges' g (Zuranolone vs. Placebo)		0.406
95% CI for Hedges' g		-0.2164, 1.0280
Day 45		
n	25	16
LS Mean (SE)	22.11 (5.059)	37.00 (6.286)
95% CI for the LS Mean	11.84, 32.37	24.26, 49.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		14.89 (8.079)
95% CI for the LS Mean		-1.49, 31.28
p-value		0.0735
Hedges' g (Zuranolone vs. Placebo)		0.579
95% CI for Hedges' g		-0.0610, 1.2187

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Age Group: 217-PPD-201B - ITT population

Page: 2 of 2

Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	24.70 (3.618)	32.11 (3.312)
95% CI for the LS Mean	17.52, 31.87	25.54, 38.68
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.42 (4.916)
95% CI for the LS Mean		-2.34, 17.17
p-value		0.1345
Hedges' g (Zuranolone vs. Placebo)		0.293
95% CI for Hedges' g		-0.0926, 0.6794
Day 45		
n	44	57
LS Mean (SE)	29.79 (3.702)	39.11 (3.280)
95% CI for the LS Mean	22.45, 37.14	32.60, 45.61
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.31 (4.961)
95% CI for the LS Mean		-0.53, 19.15
p-value		0.0633
Hedges' g (Zuranolone vs. Placebo)		0.374
95% CI for Hedges' g		-0.0228, 0.7706

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.10.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 2

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	27.01 (5.843)	31.49 (5.142)
95% CI for the LS Mean	15.25, 38.77	21.14, 41.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.48 (7.834)
95% CI for the LS Mean		-11.29, 20.24
p-value		0.5703
Hedges' g (Zuranolone vs. Placebo)		0.160
95% CI for Hedges' g		-0.3990, 0.7196
Day 45		
n	22	28
LS Mean (SE)	30.87 (5.496)	39.30 (4.842)
95% CI for the LS Mean	19.81, 41.93	29.57, 49.04
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.43 (7.385)
95% CI for the LS Mean		-6.42, 23.29
p-value		0.2592
Hedges' g (Zuranolone vs. Placebo)		0.320
95% CI for Hedges' g		-0.2417, 0.8821

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	23.42 (3.371)	32.16 (3.552)
95% CI for the LS Mean	16.72, 30.11	25.10, 39.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.74 (4.900)
95% CI for the LS Mean		-0.99, 18.47
p-value		0.0778
Hedges' g (Zuranolone vs. Placebo)		0.360
95% CI for Hedges' g		-0.0419, 0.7616
Day 45		
n	47	45
LS Mean (SE)	25.81 (3.523)	37.64 (3.624)
95% CI for the LS Mean	18.82, 32.81	30.44, 44.84
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.83 (5.059)
95% CI for the LS Mean		1.77, 21.88
p-value		0.0216
Hedges' g (Zuranolone vs. Placebo)		0.483
95% CI for Hedges' g		0.0687, 0.8982

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.10.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	22.46 (4.723)	34.35 (4.723)
95% CI for the LS Mean	13.00, 31.91	24.90, 43.80
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.90 (6.685)
95% CI for the LS Mean		-1.48, 25.28
p-value		0.0804
Hedges' g (Zuranolone vs. Placebo)		0.446
95% CI for Hedges' g		-0.0577, 0.9503
Day 45		
n	30	30
LS Mean (SE)	25.93 (4.581)	38.24 (4.581)
95% CI for the LS Mean	16.76, 35.11	29.07, 47.42
Difference (Zuranolone - Placebo)		
LS Mean (SE)		12.31 (6.486)
95% CI for the LS Mean		-0.68, 25.30
p-value		0.0627
Hedges' g (Zuranolone vs. Placebo)		0.484
95% CI for Hedges' g		-0.0296, 0.9972

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Race Group: 217-PPD-201B - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	25.16 (3.767)	30.35 (3.614)
95% CI for the LS Mean	17.66, 32.66	23.15, 37.54
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.18 (5.221)
95% CI for the LS Mean		-5.21, 15.58
p-value		0.3239
Hedges' g (Zuranolone vs. Placebo)		0.219
95% CI for Hedges' g		-0.2185, 0.6558
Day 45		
n	36	42
LS Mean (SE)	28.00 (3.911)	38.77 (3.658)
95% CI for the LS Mean	20.21, 35.78	31.49, 46.05
Difference (Zuranolone - Placebo)		
LS Mean (SE)		10.77 (5.357)
95% CI for the LS Mean		0.11, 21.44
p-value		0.0478
Hedges' g (Zuranolone vs. Placebo)		0.452
95% CI for Hedges' g		0.0014, 0.9030

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.10.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	19.56 (7.055)	36.44 (6.568)
95% CI for the LS Mean	5.04, 34.07	22.92, 49.95
Difference (Zuranolone - Placebo)		
LS Mean (SE)		16.88 (9.643)
95% CI for the LS Mean		-2.96, 36.72
p-value		0.0920
Hedges' g (Zuranolone vs. Placebo)		0.644
95% CI for Hedges' g		-0.1176, 1.4056
Day 45		
n	11	15
LS Mean (SE)	28.36 (6.813)	38.10 (5.954)
95% CI for the LS Mean	14.33, 42.39	25.80, 50.41
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.74 (9.053)
95% CI for the LS Mean		-8.93, 28.41
p-value		0.2924
Hedges' g (Zuranolone vs. Placebo)		0.414
95% CI for Hedges' g		-0.3724, 1.1998

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 2 of 2

Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	25.49 (3.206)	30.92 (3.226)
95% CI for the LS Mean	19.14, 31.85	24.53, 37.31
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.43 (4.550)
95% CI for the LS Mean		-3.59, 14.44
p-value		0.2355
Hedges' g (Zuranolone vs. Placebo)		0.217
95% CI for Hedges' g		-0.1431, 0.5777
Day 45		
n	58	58
LS Mean (SE)	27.20 (3.283)	38.43 (3.284)
95% CI for the LS Mean	20.70, 33.70	31.93, 44.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.24 (4.646)
95% CI for the LS Mean		2.03, 20.44
p-value		0.0172
Hedges' g (Zuranolone vs. Placebo)		0.446
95% CI for Hedges' g		0.0776, 0.8146

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.10.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	25.60 (5.938)	32.01 (7.399)
95% CI for the LS Mean	13.45, 37.74	16.88, 47.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.41 (9.552)
95% CI for the LS Mean		-13.12, 25.95
p-value		0.5072
Hedges' g (Zuranolone vs. Placebo)		0.233
95% CI for Hedges' g		-0.4671, 0.9339
Day 45		
n	18	12
LS Mean (SE)	24.65 (6.207)	45.78 (7.645)
95% CI for the LS Mean	11.93, 37.37	30.11, 61.46
Difference (Zuranolone - Placebo)		
LS Mean (SE)		21.13 (9.922)
95% CI for the LS Mean		0.80, 41.46
p-value		0.0422
Hedges' g (Zuranolone vs. Placebo)		0.772
95% CI for Hedges' g		0.0161, 1.5283

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	24.35 (6.124)	33.13 (6.066)
95% CI for the LS Mean	11.93, 36.77	20.84, 45.42
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.77 (8.646)
95% CI for the LS Mean		-8.75, 26.30
p-value		0.3169
Hedges' g (Zuranolone vs. Placebo)		0.314
95% CI for Hedges' g		-0.3091, 0.9381
Day 45		
n	20	20
LS Mean (SE)	32.60 (5.370)	42.31 (5.330)
95% CI for the LS Mean	21.71, 43.49	31.52, 53.11
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.71 (7.604)
95% CI for the LS Mean		-5.70, 25.12
p-value		0.2096
Hedges' g (Zuranolone vs. Placebo)		0.396
95% CI for Hedges' g		-0.2301, 1.0216

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	23.44 (4.108)	31.55 (3.684)
95% CI for the LS Mean	15.24, 31.63	24.21, 38.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.12 (5.529)
95% CI for the LS Mean		-2.91, 19.14
p-value		0.1465
Hedges' g (Zuranolone vs. Placebo)		0.340
95% CI for Hedges' g		-0.1218, 0.8014
Day 45		
n	31	41
LS Mean (SE)	25.09 (4.426)	34.60 (3.871)
95% CI for the LS Mean	16.27, 33.92	26.88, 42.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.51 (5.891)
95% CI for the LS Mean		-2.24, 21.26
p-value		0.1109
Hedges' g (Zuranolone vs. Placebo)		0.380
95% CI for Hedges' g		-0.0905, 0.8507

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.10.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	20.32 (4.559)	31.71 (4.487)
95% CI for the LS Mean	11.20, 29.44	22.73, 40.69
Difference (Zuranolone - Placebo)		
LS Mean (SE)		11.39 (6.402)
95% CI for the LS Mean		-1.42, 24.20
p-value		0.0805
Hedges' g (Zuranolone vs. Placebo)		0.443
95% CI for Hedges' g		-0.0572, 0.9427
Day 45		
n	29	30
LS Mean (SE)	25.52 (4.733)	41.26 (4.654)
95% CI for the LS Mean	16.04, 35.00	31.94, 50.58
Difference (Zuranolone - Placebo)		
LS Mean (SE)		15.74 (6.644)
95% CI for the LS Mean		2.43, 29.05
p-value		0.0213
Hedges' g (Zuranolone vs. Placebo)		0.609
95% CI for Hedges' g		0.0866, 1.1307

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	27.34 (3.699)	32.38 (3.686)
95% CI for the LS Mean	19.98, 34.70	25.05, 39.72
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.04 (5.232)
95% CI for the LS Mean		-5.37, 15.46
p-value		0.3379
Hedges' g (Zuranolone vs. Placebo)		0.208
95% CI for Hedges' g		-0.2204, 0.6373
Day 45		
n	40	43
LS Mean (SE)	28.62 (3.804)	36.46 (3.696)
95% CI for the LS Mean	21.06, 36.19	29.11, 43.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.84 (5.314)
95% CI for the LS Mean		-2.73, 18.41
p-value		0.1439
Hedges' g (Zuranolone vs. Placebo)		0.321
95% CI for Hedges' g		-0.1121, 0.7545

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.10.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	23.99 (6.434)	23.62 (6.463)
95% CI for the LS Mean	10.39, 37.58	9.97, 37.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.37 (9.489)
95% CI for the LS Mean		-20.38, 19.64
p-value		0.9696
Hedges' g (Zuranolone vs. Placebo)		-0.017
95% CI for Hedges' g		-0.8931, 0.8600
Day 45		
n	9	10
LS Mean (SE)	28.46 (7.031)	22.62 (6.688)
95% CI for the LS Mean	13.65, 43.27	8.46, 36.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-5.84 (10.108)
95% CI for the LS Mean		-27.11, 15.42
p-value		0.5705
Hedges' g (Zuranolone vs. Placebo)		-0.254
95% CI for Hedges' g		-1.1579, 0.6504

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	24.75 (3.242)	33.03 (3.210)
95% CI for the LS Mean	18.34, 31.17	26.67, 39.38
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.27 (4.563)
95% CI for the LS Mean		-0.76, 17.31
p-value		0.0723
Hedges' g (Zuranolone vs. Placebo)		0.320
95% CI for Hedges' g		-0.0302, 0.6699
Day 45		
n	60	63
LS Mean (SE)	27.46 (3.224)	40.54 (3.154)
95% CI for the LS Mean	21.07, 33.84	34.29, 46.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		13.08 (4.511)
95% CI for the LS Mean		4.15, 22.01
p-value		0.0044
Hedges' g (Zuranolone vs. Placebo)		0.520
95% CI for Hedges' g		0.1603, 0.8793

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.10.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	25.90 (3.253)	32.91 (3.117)
95% CI for the LS Mean	19.46, 32.34	26.74, 39.08
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.01 (4.506)
95% CI for the LS Mean		-1.91, 15.94
p-value		0.1222
Hedges' g (Zuranolone vs. Placebo)		0.279
95% CI for Hedges' g		-0.0763, 0.6347
Day 45		
n	55	64
LS Mean (SE)	28.35 (3.376)	38.54 (3.150)
95% CI for the LS Mean	21.67, 35.04	32.30, 44.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		10.19 (4.618)
95% CI for the LS Mean		1.05, 19.34
p-value		0.0293
Hedges' g (Zuranolone vs. Placebo)		0.403
95% CI for Hedges' g		0.0392, 0.7671

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	18.11 (6.687)	26.88 (7.955)
95% CI for the LS Mean	4.20, 32.02	10.34, 43.42
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.77 (10.703)
95% CI for the LS Mean		-13.46, 30.99
p-value		0.4217
Hedges' g (Zuranolone vs. Placebo)		0.327
95% CI for Hedges' g		-0.4893, 1.1442
Day 45		
n	14	9
LS Mean (SE)	22.75 (6.261)	37.76 (7.829)
95% CI for the LS Mean	9.68, 35.83	21.50, 54.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		15.00 (10.398)
95% CI for the LS Mean		-6.60, 36.60
p-value		0.1635
Hedges' g (Zuranolone vs. Placebo)		0.594
95% CI for Hedges' g		-0.2606, 1.4491

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

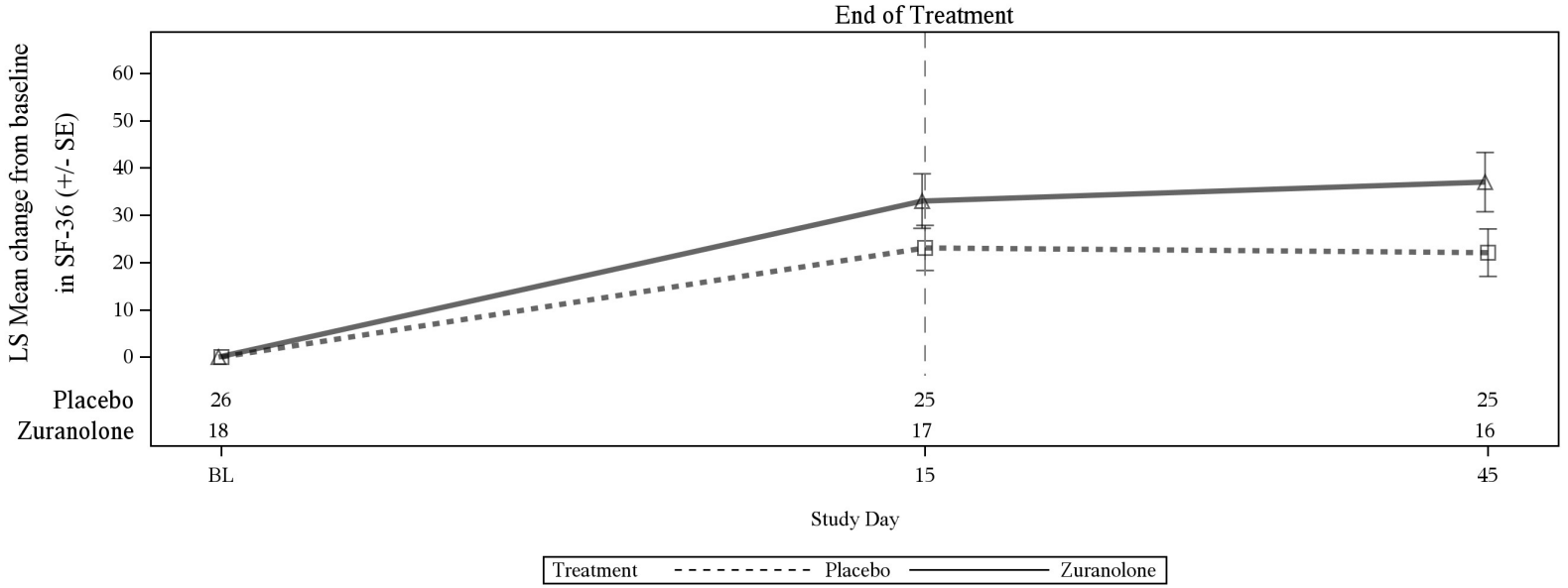
Source: biib125/v_a/germany_amnog/t-sf36-mh-mmrm-201-by.sas:t-sf36-mh-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.10.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

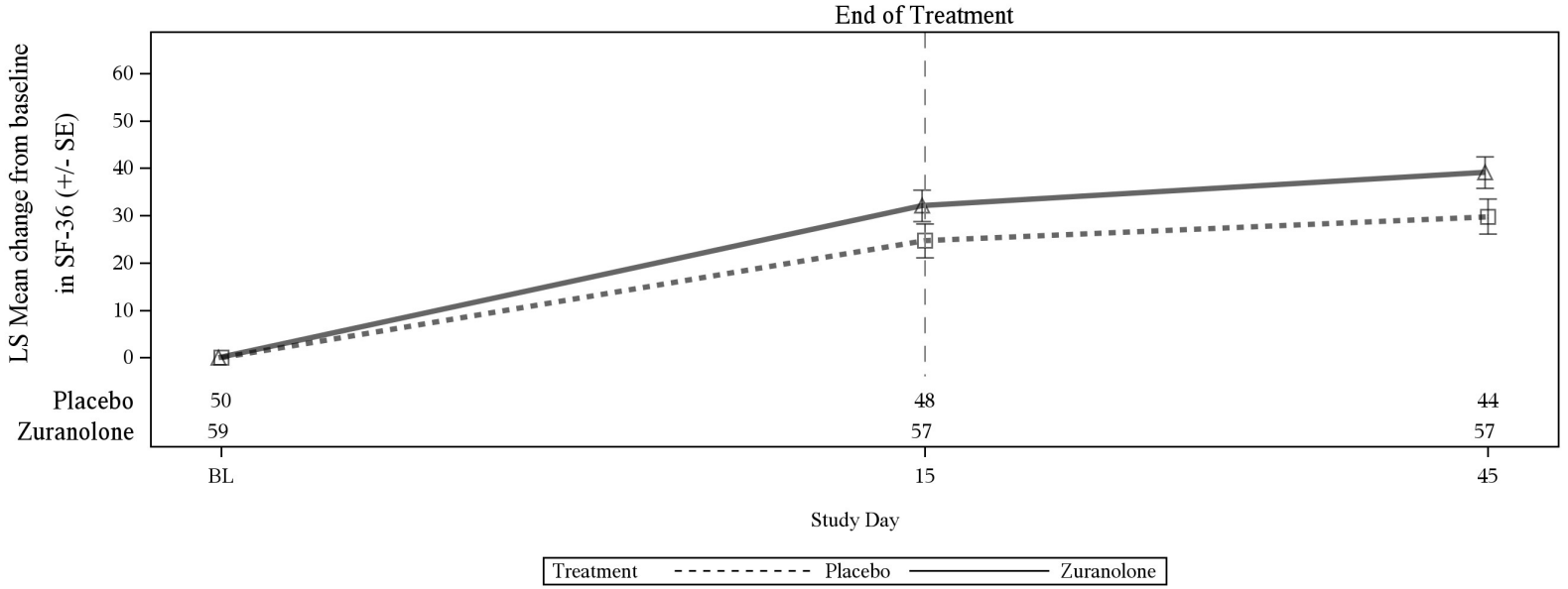
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Source: biib125/v_a/germany_amnog/f-sf36-mh-mmrm-201-by.sas:f-sf36-mh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

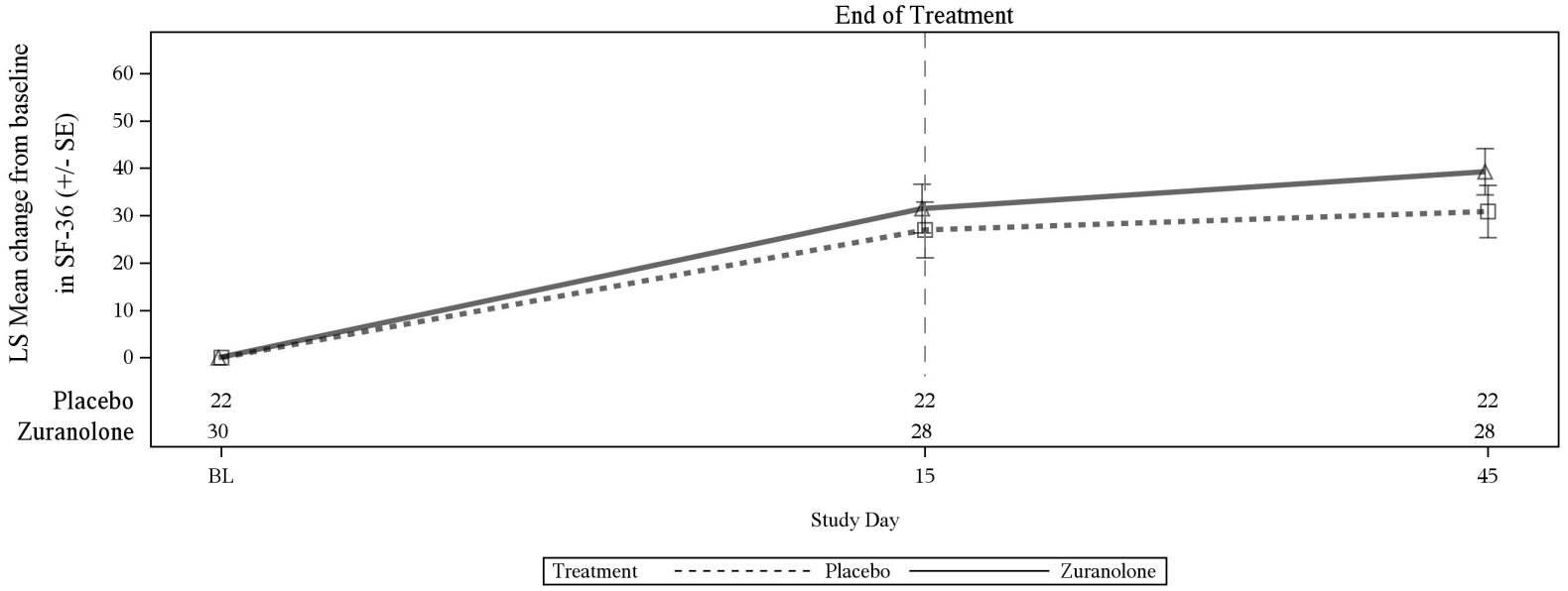
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

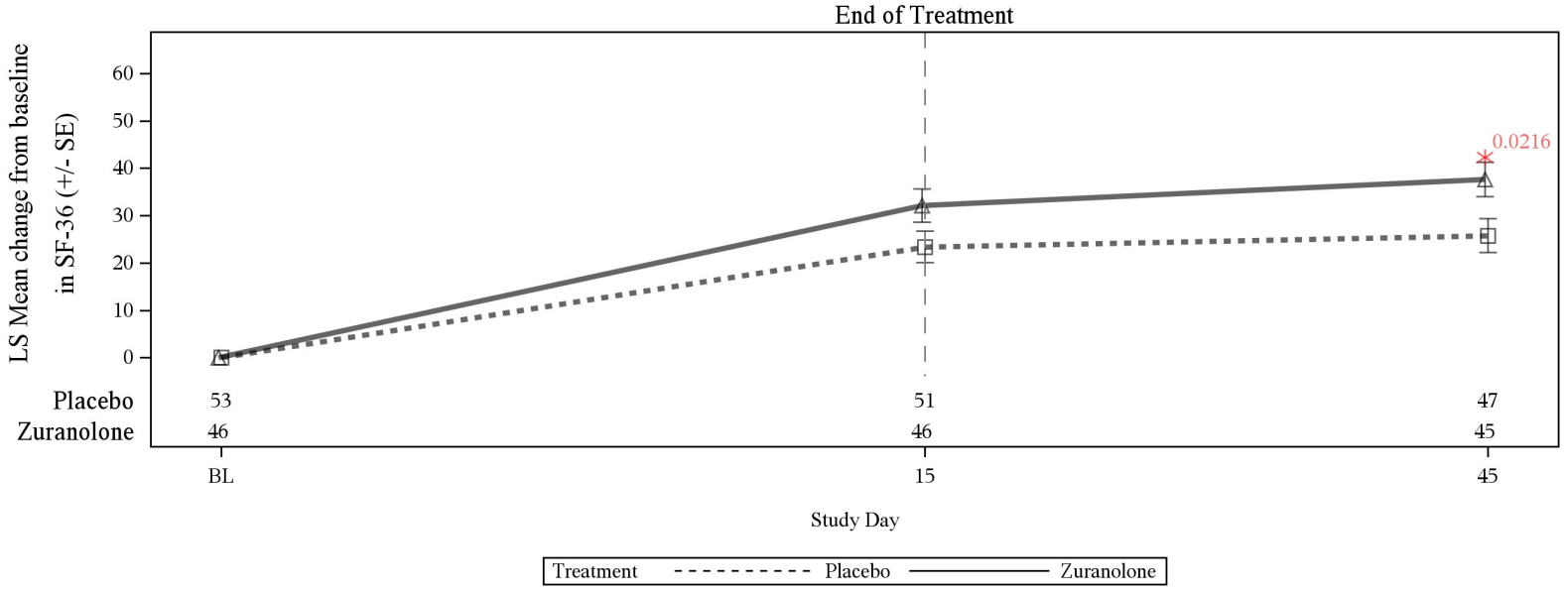
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

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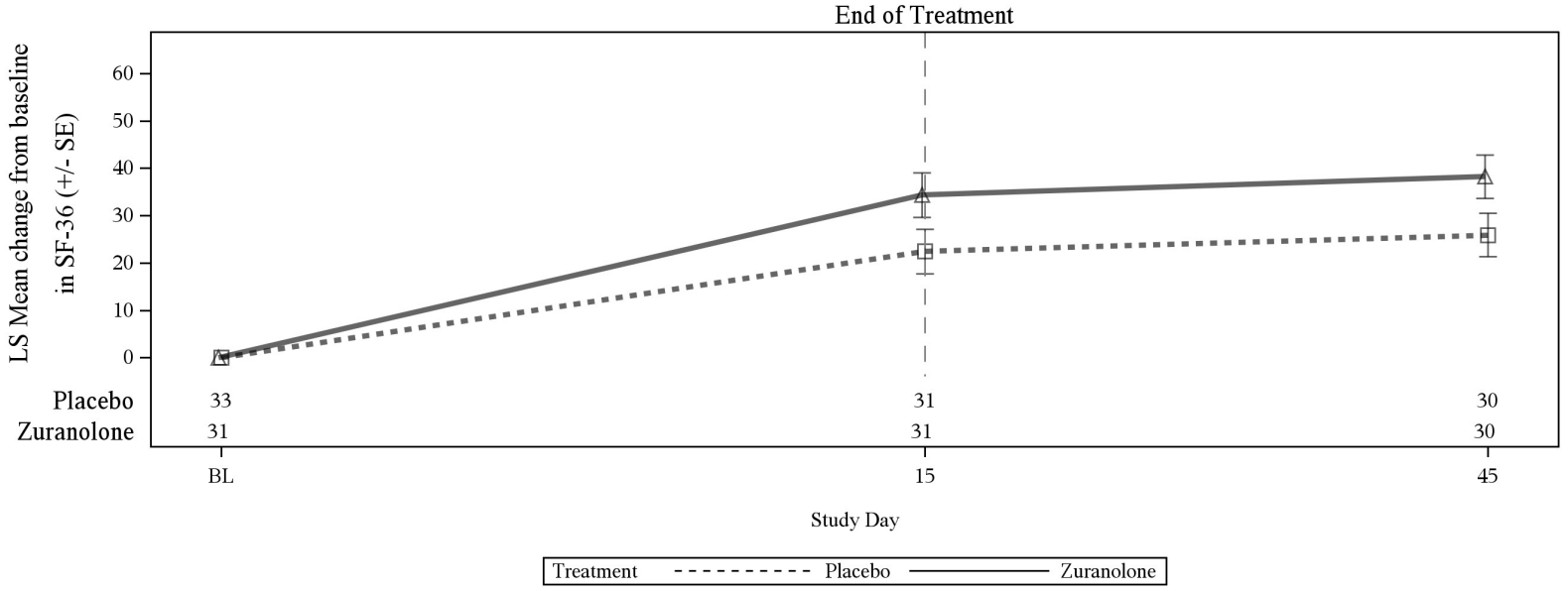
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

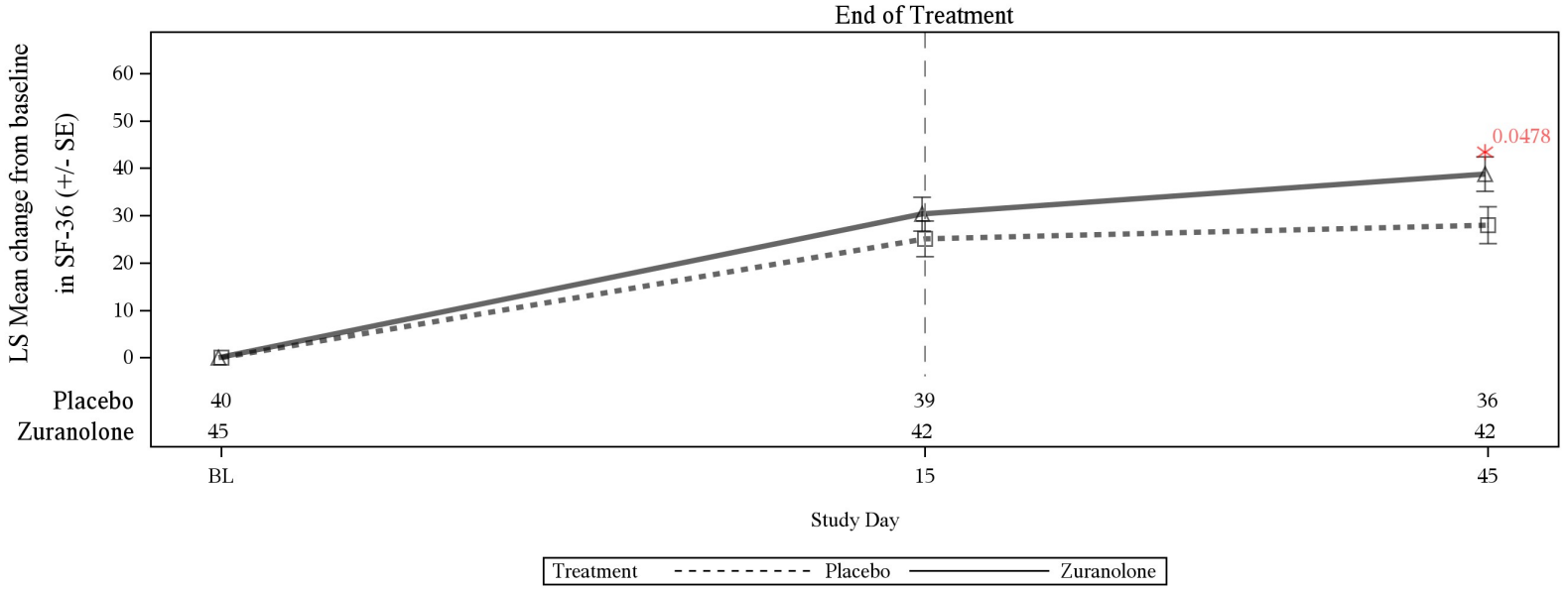
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

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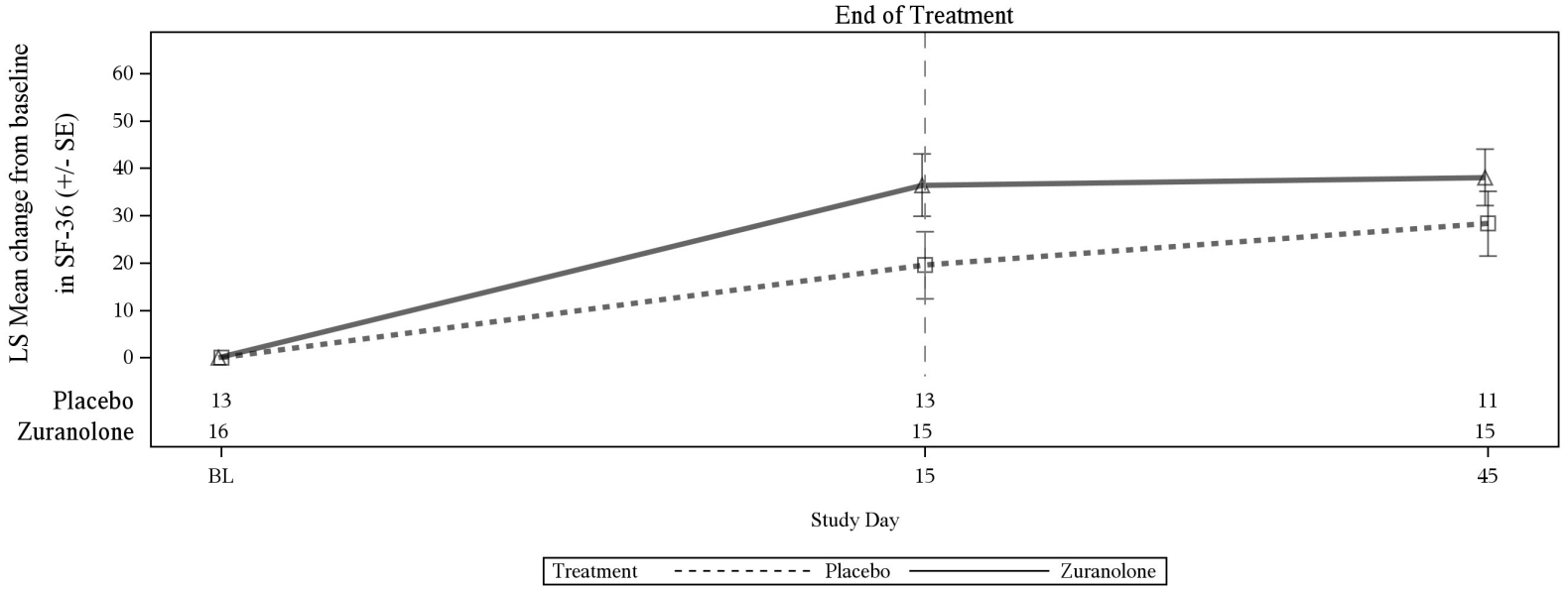
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 7 of 17

Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

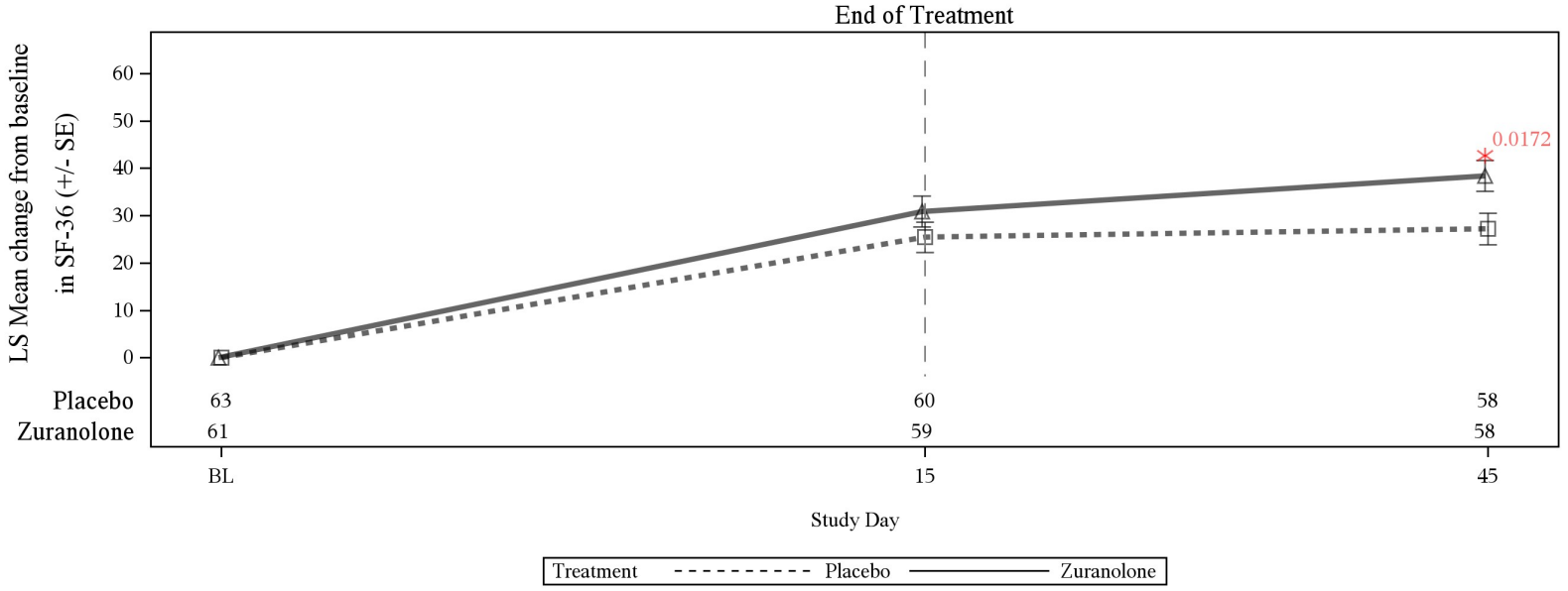
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

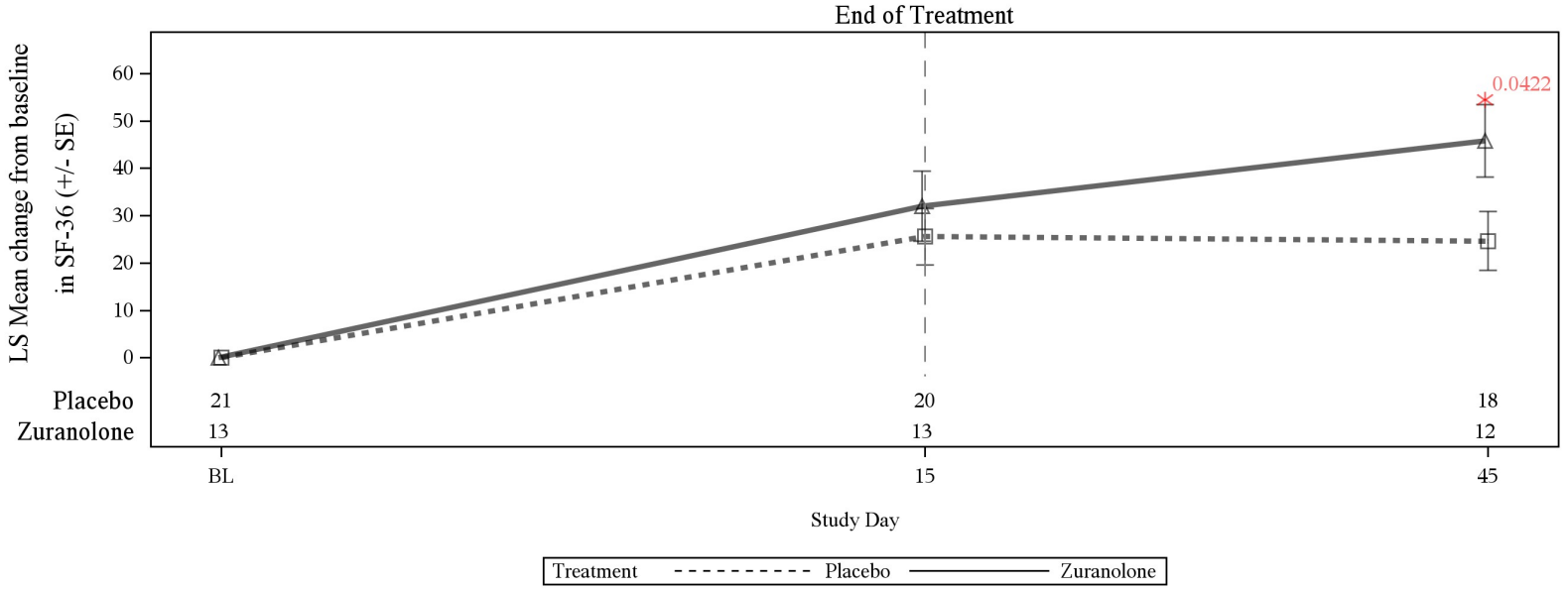
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 9 of 17

BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

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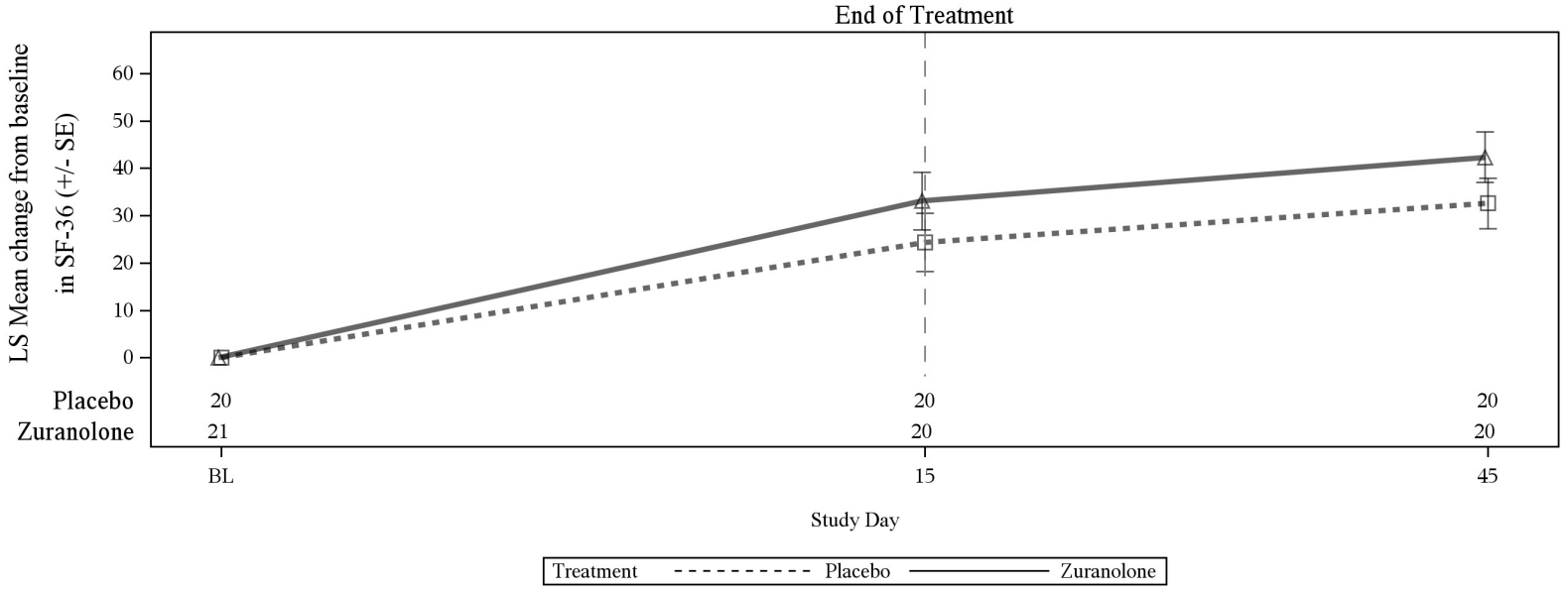
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 10 of 17

BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

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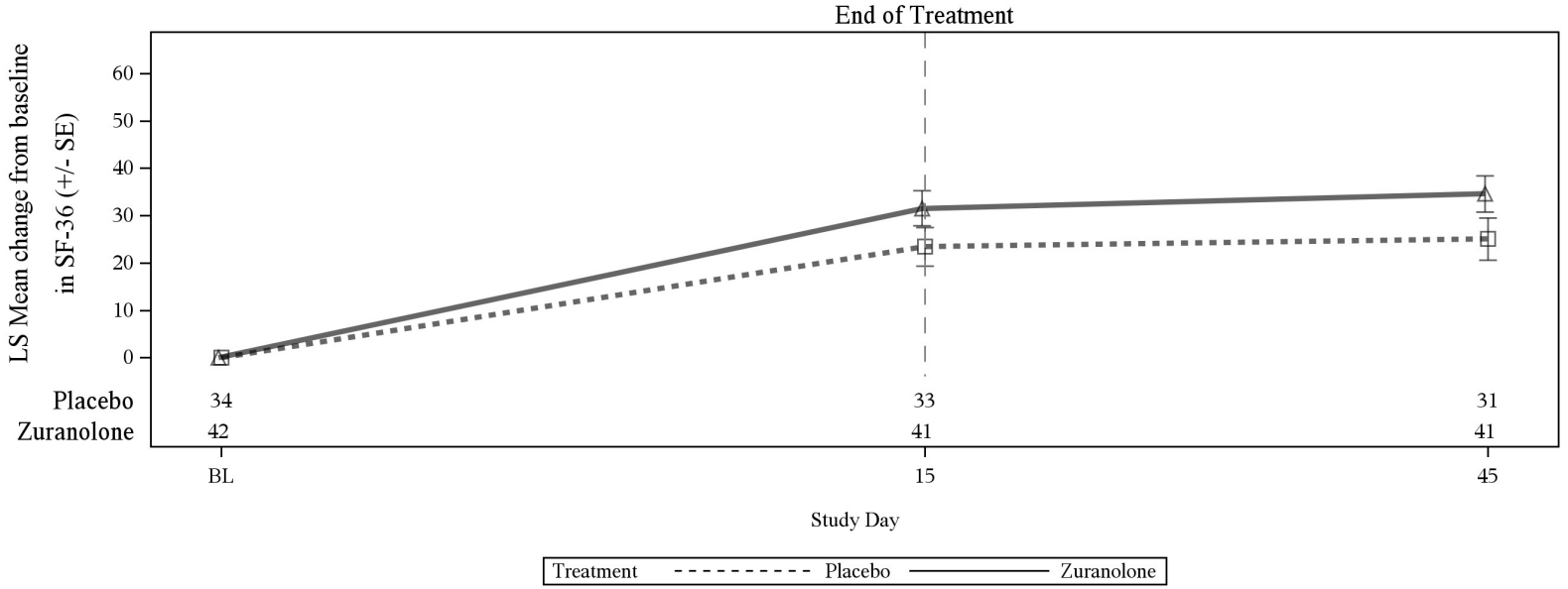
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 11 of 17

BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

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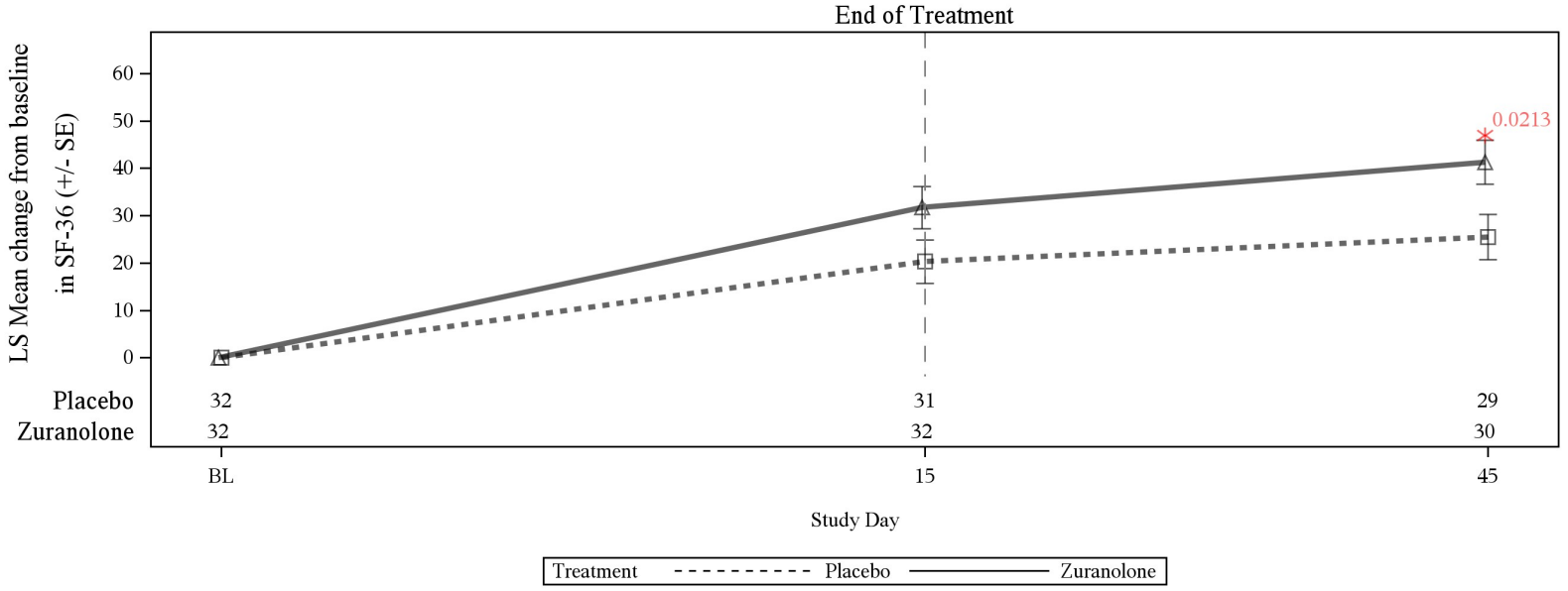
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

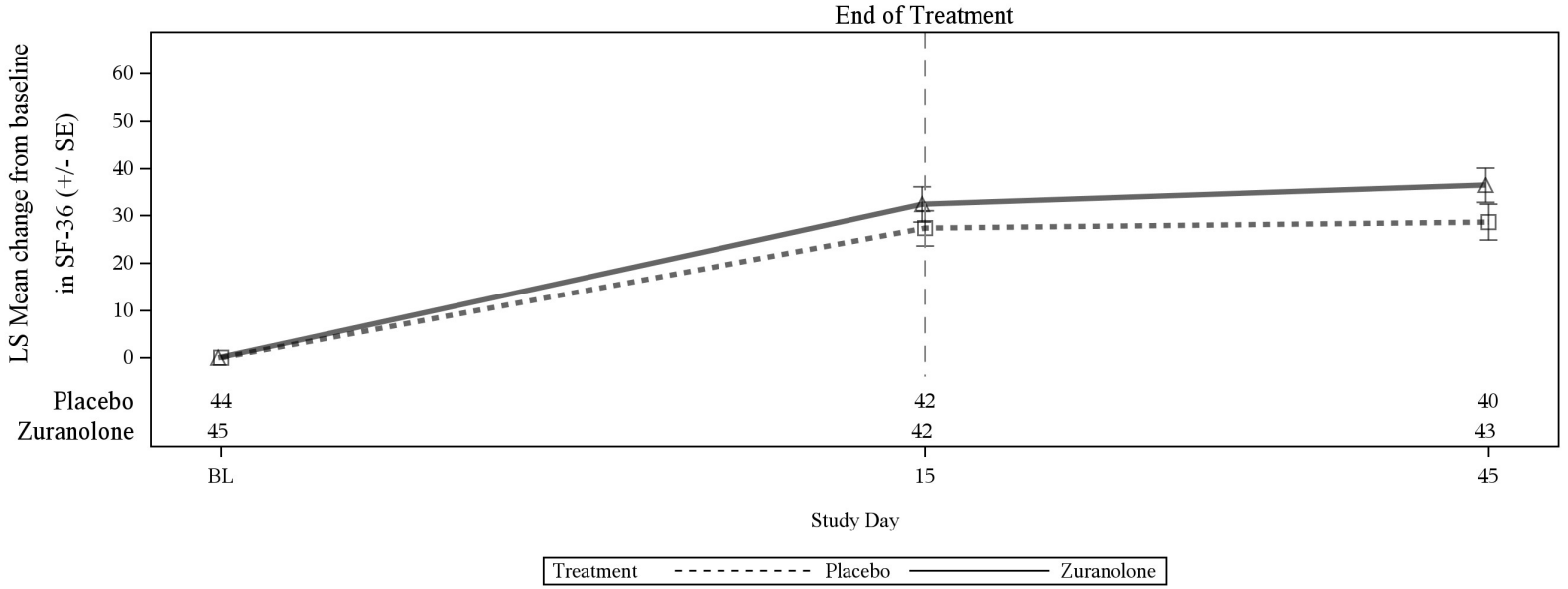
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 13 of 17

Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

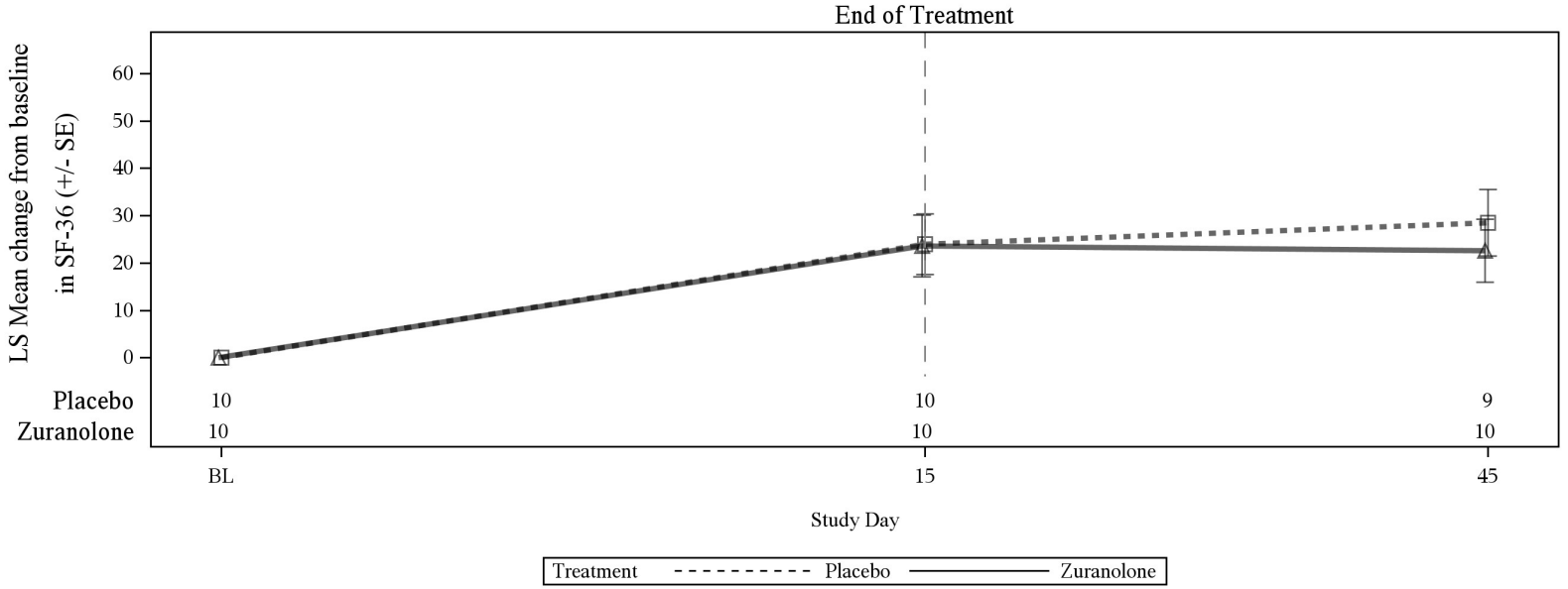
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Source: biib125/v_a/germany_amnog/f-sf36-mh-mmrm-201-by.sas:f-sf36-mh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

Page: 14 of 17

Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

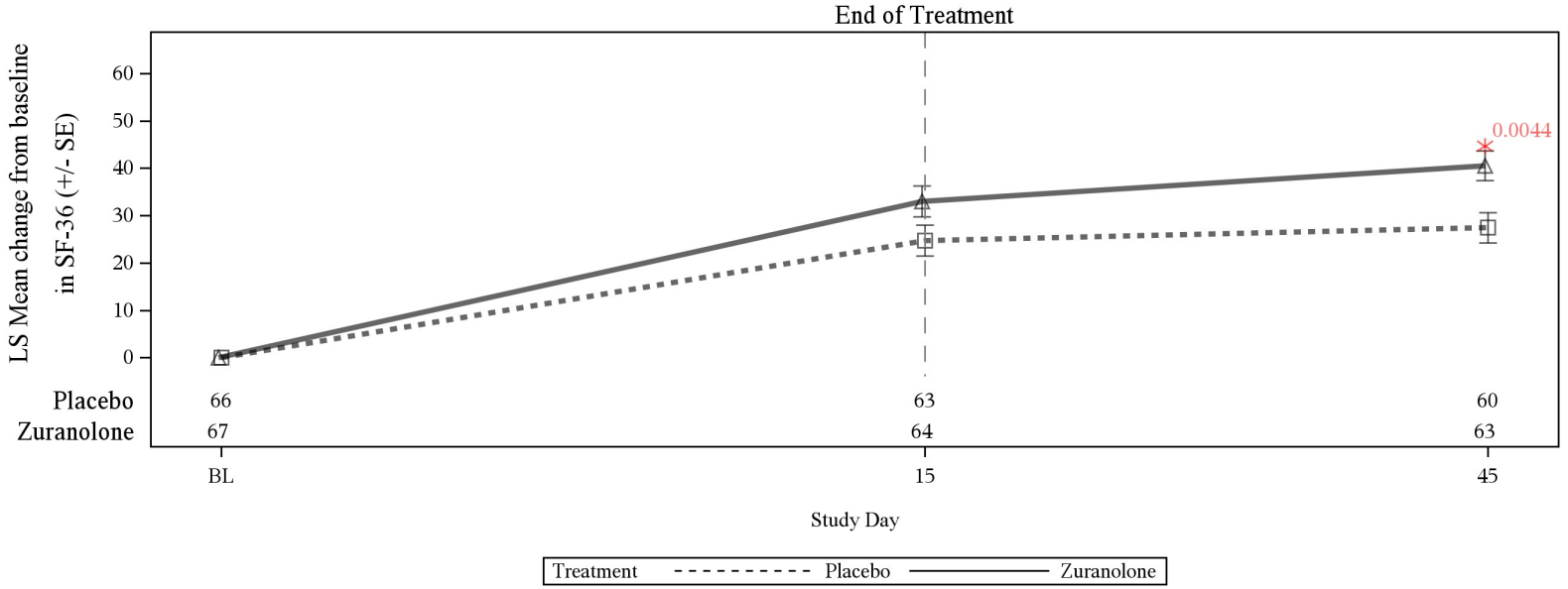
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Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

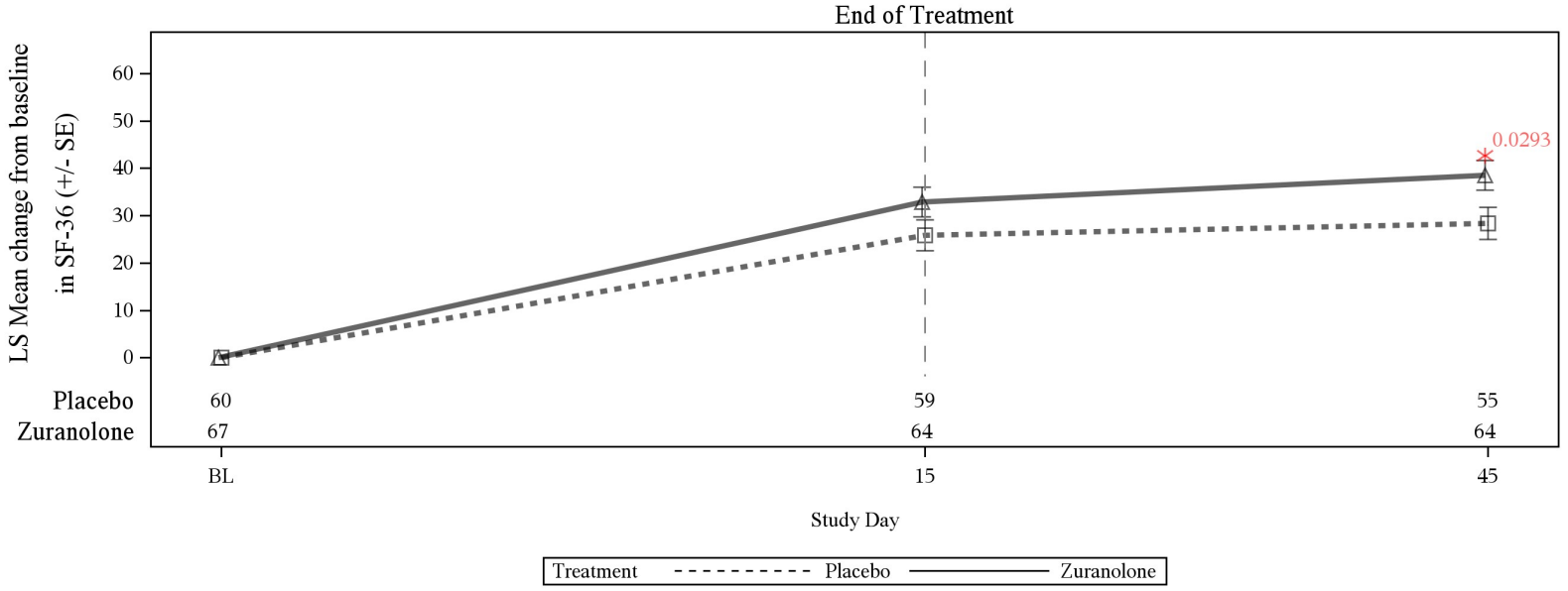
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-mh-mmrm-201-by.sas:f-sf36-mh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

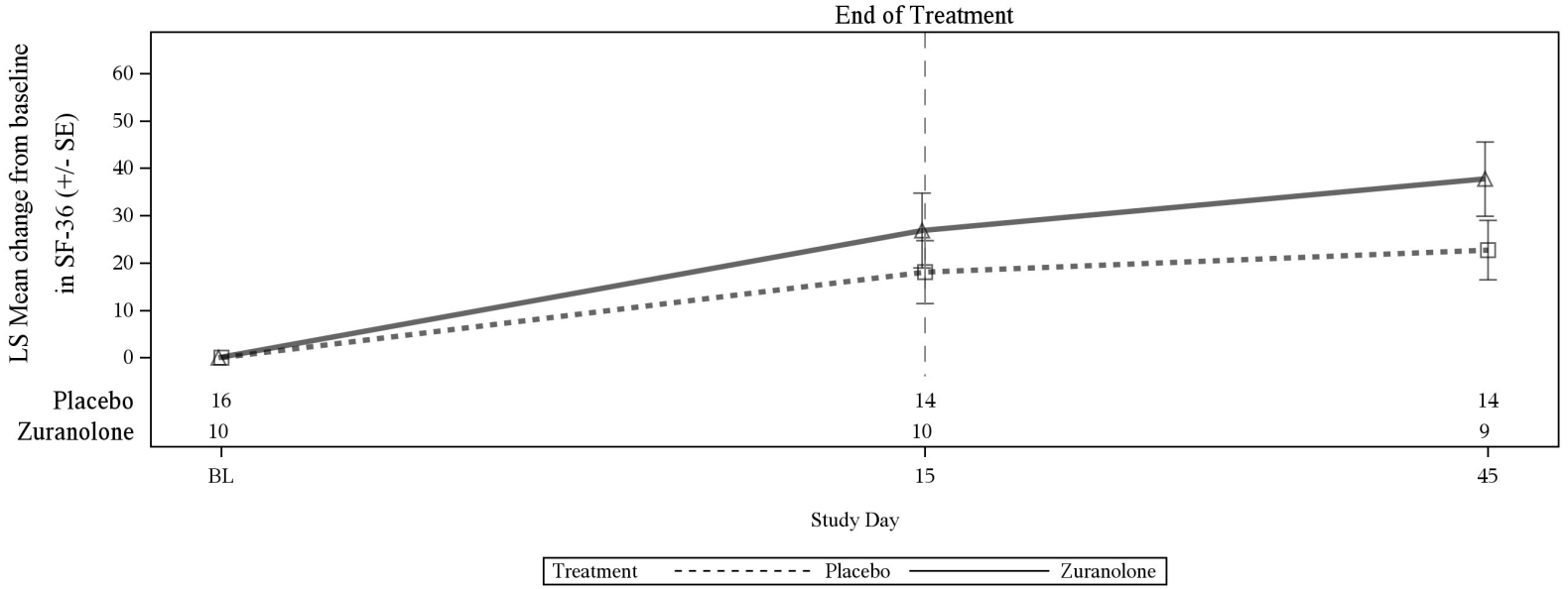
NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-mh-mmrm-201-by.sas:f-sf36-mh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Short-Form 36 (SF-36) Mental Health Subscale by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The SF-36 Health Survey is a subject-reported 36-item instrument for measuring functional health and well-being in 8 dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The Physical Component Summary and the Mental Component Summary are derived from the 8 dimensions. All dimension and component summary scores are norm-based. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-sf36-mh-mmrm-201-by.sas:f-sf36-mh-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

2.10.2 Ansprechen

2.10.2.1 Responder-Analysen

2.10.2.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with a response, n (%) [2]	47 (62.7)	54 (71.1)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.149
95% CI for the RR		(0.918, 1.439)
p-value for RR		0.2253
OR - Odds Ratio (Zuranolone vs. Placebo)		1.549
95% CI for the OR		(0.775, 3.098)
p-value for OR		0.2157
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.110
95% CI for the ARR		(-0.038, 0.258)
p-value for ARR		0.1464

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-ovr.sas:t-sf36-mh-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	50 (66.7)	62 (81.6)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.240
95% CI for the RR		(1.028, 1.497)
p-value for RR		0.0249
OR - Odds Ratio (Zuranolone vs. Placebo)		2.380
95% CI for the OR		(1.127, 5.028)
p-value for OR		0.0230
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.182
95% CI for the ARR		(0.054, 0.309)
p-value for ARR		0.0053

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score (for the respective parameter), treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-ovr.sas:t-sf36-mh-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.10.2.1 .2 Subgruppen

2.10.2.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	47 (62.7)	54 (71.1)	
Number of subjects with response at Day 45, n (%)	50 (66.7)	62 (81.6)	
Age Group (years)			0.7202
Day 15			
18 - 24, n / N (%)	17/25 (68.0)	15/17 (88.2)	
25 - 45, n / N (%)	30/50 (60.0)	39/59 (66.1)	
Day 45			
18 - 24, n / N (%)	17/25 (68.0)	12/17 (70.6)	
25 - 45, n / N (%)	33/50 (66.0)	50/59 (84.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-int.sas:t-sf36-mh-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.0842
Day 15			
<28, n / N (%)	16/22 (72.7)	20/30 (66.7)	
>=28, n / N (%)	31/53 (58.5)	34/46 (73.9)	
Day 45			
<28, n / N (%)	18/22 (81.8)	24/30 (80.0)	
>=28, n / N (%)	32/53 (60.4)	38/46 (82.6)	
Race Group (Black or African American, White)			0.6531
Day 15			
Black or African American, n / N (%)	19/32 (59.4)	23/31 (74.2)	
White, n / N (%)	26/40 (65.0)	30/44 (68.2)	
Day 45			
Black or African American, n / N (%)	22/32 (68.8)	26/31 (83.9)	
White, n / N (%)	26/40 (65.0)	35/44 (79.5)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-int.sas:t-sf36-mh-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.4569
Day 15			
Yes, n / N (%)	7/13 (53.8)	12/16 (75.0)	
No, n / N (%)	40/62 (64.5)	42/60 (70.0)	
Day 45			
Yes, n / N (%)	8/13 (61.5)	13/16 (81.3)	
No, n / N (%)	42/62 (67.7)	49/60 (81.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-int.sas:t-sf36-mh-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.4533(a) 0.6886(b) 0.1624(c)
Day 15			
<=24.9, n / N (%)	14/21 (66.7)	9/13 (69.2)	
25-29.9, n / N (%)	14/20 (70.0)	13/21 (61.9)	
>=30, n / N (%)	19/34 (55.9)	32/42 (76.2)	
Day 45			
<=24.9, n / N (%)	11/21 (52.4)	10/13 (76.9)	
25-29.9, n / N (%)	16/20 (80.0)	18/21 (85.7)	
>=30, n / N (%)	23/34 (67.6)	34/42 (81.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-int.sas:t-sf36-mh-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.2206
Day 15			
3rd Trimester, n / N (%)	18/32 (56.3)	24/32 (75.0)	
Postpartum, n / N (%)	29/43 (67.4)	30/44 (68.2)	
Day 45			
3rd Trimester, n / N (%)	20/32 (62.5)	27/32 (84.4)	
Postpartum, n / N (%)	30/43 (69.8)	35/44 (79.5)	
Family History of PPD			0.4189
Day 15			
Yes, n / N (%)	8/10 (80.0)	6/10 (60.0)	
No/Unknown, n / N (%)	39/65 (60.0)	48/66 (72.7)	
Day 45			
Yes, n / N (%)	7/10 (70.0)	8/10 (80.0)	
No/Unknown, n / N (%)	43/65 (66.2)	54/66 (81.8)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-int.sas:t-sf36-mh-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.4385
Day 15			
1st Episode, n / N (%)	39/59 (66.1)	48/66 (72.7)	
Recurrent Episode, n / N (%)	8/16 (50.0)	6/10 (60.0)	
Day 45			
1st Episode, n / N (%)	40/59 (67.8)	53/66 (80.3)	
Recurrent Episode, n / N (%)	10/16 (62.5)	9/10 (90.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	4/8 (50.0)	7/10 (70.0)	
>=20, n / N (%)	43/67 (64.2)	47/66 (71.2)	
Day 45			
<20, n / N (%)	5/8 (62.5)	8/10 (80.0)	
>=20, n / N (%)	45/67 (67.2)	54/66 (81.8)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-int.sas:t-sf36-mh-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

2.10.2.1 .2 .2 Subgruppenanalysen

2.10.2.1 .2 .2 .1 Alter

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 15		
Number of subjects with a response, n (%) [2]	17 (68.0)	15 (88.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.303
95% CI for the RR		(0.941, 1.803)
p-value for RR		0.1112
Day 45		
Number of subjects with a response, n (%) [2]	17 (68.0)	12 (70.6)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.042
95% CI for the RR		(0.695, 1.562)
p-value for RR		0.8420

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 15		
Number of subjects with a response, n (%) [2]	30 (60.0)	39 (66.1)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.139
95% CI for the RR		(0.856, 1.516)
p-value for RR		0.3717
Day 45		
Number of subjects with a response, n (%) [2]	33 (66.0)	50 (84.7)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.328
95% CI for the RR		(1.062, 1.660)
p-value for RR		0.0129

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.10.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 15		
Number of subjects with a response, n (%) [2]	16 (72.7)	20 (66.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.941
95% CI for the RR		(0.660, 1.342)
p-value for RR		0.7371
Day 45		
Number of subjects with a response, n (%) [2]	18 (81.8)	24 (80.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.004
95% CI for the RR		(0.776, 1.299)
p-value for RR		0.9774

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 15		
Number of subjects with a response, n (%) [2]	31 (58.5)	34 (73.9)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.266
95% CI for the RR		(0.953, 1.682)
p-value for RR		0.1035
Day 45		
Number of subjects with a response, n (%) [2]	32 (60.4)	38 (82.6)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.371
95% CI for the RR		(1.068, 1.760)
p-value for RR		0.0134

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.10.2.1 .2 .2 .3 Abstammung

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 15		
Number of subjects with a response, n (%) [2]	19 (59.4)	23 (74.2)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.267
95% CI for the RR		(0.891, 1.802)
p-value for RR		0.1882
Day 45		
Number of subjects with a response, n (%) [2]	22 (68.8)	26 (83.9)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.237
95% CI for the RR		(0.950, 1.610)
p-value for RR		0.1138

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 15		
Number of subjects with a response, n (%) [2]	26 (65.0)	30 (68.2)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.065
95% CI for the RR		(0.791, 1.433)
p-value for RR		0.6782
Day 45		
Number of subjects with a response, n (%) [2]	26 (65.0)	35 (79.5)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.242
95% CI for the RR		(0.951, 1.624)
p-value for RR		0.1122

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.10.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 15		
Number of subjects with a response, n (%) [2]	7 (53.8)	12 (75.0)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.419
95% CI for the RR		(0.803, 2.508)
p-value for RR		0.2281
Day 45		
Number of subjects with a response, n (%) [2]	8 (61.5)	13 (81.3)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.345
95% CI for the RR		(0.837, 2.163)
p-value for RR		0.2205

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 15		
Number of subjects with a response, n (%) [2]	40 (64.5)	42 (70.0)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.096
95% CI for the RR		(0.856, 1.403)
p-value for RR		0.4660
Day 45		
Number of subjects with a response, n (%) [2]	42 (67.7)	49 (81.7)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.218
95% CI for the RR		(0.992, 1.496)
p-value for RR		0.0599

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.10.2.1 .2 .2 .5 BMI

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 15		
Number of subjects with a response, n (%) [2]	14 (66.7)	9 (69.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.045
95% CI for the RR		(0.647, 1.688)
p-value for RR		0.8573
Day 45		
Number of subjects with a response, n (%) [2]	11 (52.4)	10 (76.9)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.478
95% CI for the RR		(0.893, 2.446)
p-value for RR		0.1287

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 15		
Number of subjects with a response, n (%) [2]	14 (70.0)	13 (61.9)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.905
95% CI for the RR		(0.589, 1.391)
p-value for RR		0.6495
Day 45		
Number of subjects with a response, n (%) [2]	16 (80.0)	18 (85.7)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.097
95% CI for the RR		(0.832, 1.445)
p-value for RR		0.5123

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 15		
Number of subjects with a response, n (%) [2]	19 (55.9)	32 (76.2)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.418
95% CI for the RR		(1.011, 1.991)
p-value for RR		0.0433
Day 45		
Number of subjects with a response, n (%) [2]	23 (67.6)	34 (81.0)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.245
95% CI for the RR		(0.950, 1.631)
p-value for RR		0.1117

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.10.2.1 .2 .2 .6 Beginn der PPD

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 15		
Number of subjects with a response, n (%) [2]	18 (56.3)	24 (75.0)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.342
95% CI for the RR		(0.929, 1.937)
p-value for RR		0.1169
Day 45		
Number of subjects with a response, n (%) [2]	20 (62.5)	27 (84.4)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.358
95% CI for the RR		(1.001, 1.843)
p-value for RR		0.0492

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 15		
Number of subjects with a response, n (%) [2]	29 (67.4)	30 (68.2)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.037
95% CI for the RR		(0.785, 1.371)
p-value for RR		0.7971
Day 45		
Number of subjects with a response, n (%) [2]	30 (69.8)	35 (79.5)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.170
95% CI for the RR		(0.917, 1.492)
p-value for RR		0.2071

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.10.2.1 .2 .2 .7 PPD in der Familie

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 15		
Number of subjects with a response, n (%) [2]	8 (80.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.876
95% CI for the RR		(0.506, 1.517)
p-value for RR		0.6371
Day 45		
Number of subjects with a response, n (%) [2]	7 (70.0)	8 (80.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.335
95% CI for the RR		(0.814, 2.192)
p-value for RR		0.2525

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 15		
Number of subjects with a response, n (%) [2]	39 (60.0)	48 (72.7)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.214
95% CI for the RR		(0.948, 1.555)
p-value for RR		0.1250
Day 45		
Number of subjects with a response, n (%) [2]	43 (66.2)	54 (81.8)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.238
95% CI for the RR		(1.008, 1.521)
p-value for RR		0.0414

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.10.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 15		
Number of subjects with a response, n (%) [2]	39 (66.1)	48 (72.7)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.104
95% CI for the RR		(0.873, 1.397)
p-value for RR		0.4095
Day 45		
Number of subjects with a response, n (%) [2]	40 (67.8)	53 (80.3)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.188
95% CI for the RR		(0.966, 1.463)
p-value for RR		0.1031

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 15		
Number of subjects with a response, n (%) [2]	8 (50.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.252
95% CI for the RR		(0.596, 2.631)
p-value for RR		0.5532
Day 45		
Number of subjects with a response, n (%) [2]	10 (62.5)	9 (90.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.502
95% CI for the RR		(0.874, 2.582)
p-value for RR		0.1406

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score response (15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

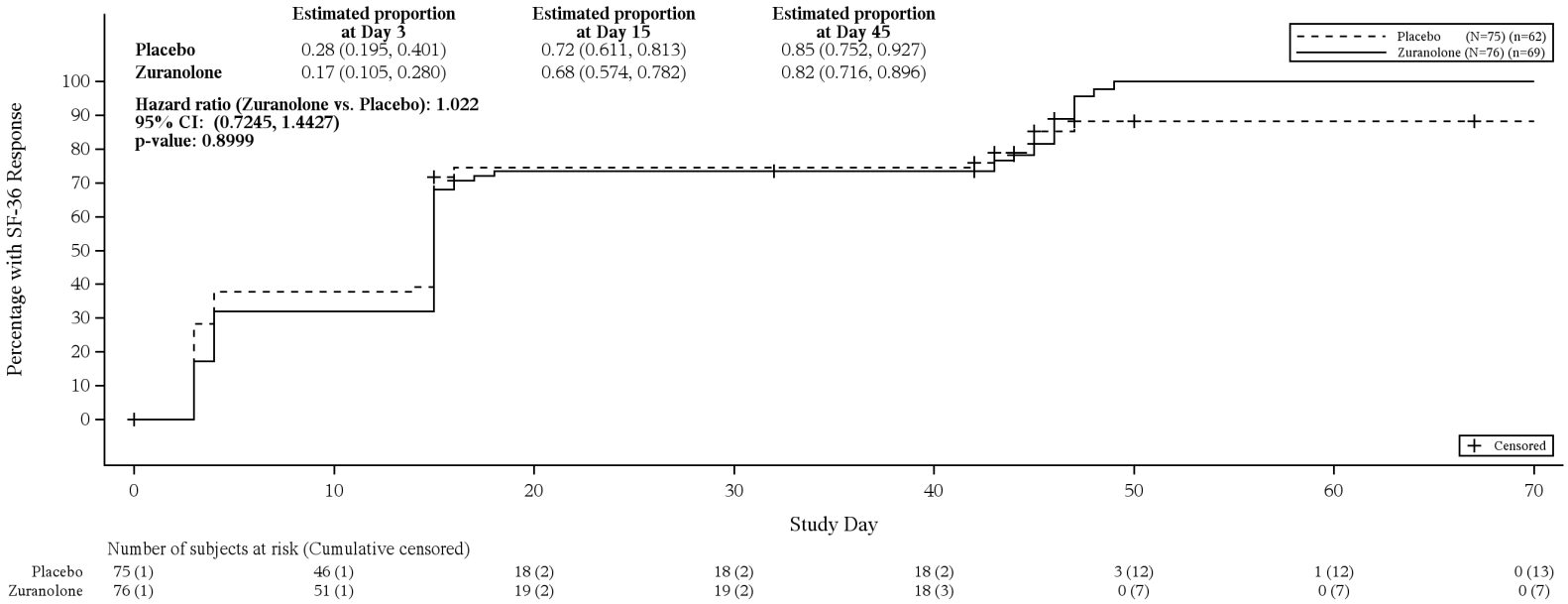
Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-201-by.sas:t-sf36-mh-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.10.2.2 TTE-Analysen

2.10.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-ovr.sas:f-sf36-mh-resp15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	62 (82.7)	69 (90.8)
Time to first SF-36 Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (14.0 , 15.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	42.0 (15.0 , 45.0)	43.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.022
95% CI for the HR		(0.7245 , 1.4427)
p-value for the HR		0.8999

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-ovr.sas:t-sf36-mh-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.10.2.2 .2 Subgruppen

2.10.2.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	62 (82.7)	69 (90.8)	
Age Group (years)			
18 - 24, n / N (%)	22/25 (88.0)	17/17 (100.0)	0.3366
25 - 45, n / N (%)	40/50 (80.0)	52/59 (88.1)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	20/22 (90.9)	26/30 (86.7)	0.5922
>=28, n / N (%)	42/53 (79.2)	43/46 (93.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	26/32 (81.3)	30/31 (96.8)	0.7326
White, n / N (%)	33/40 (82.5)	38/44 (86.4)	
Antidepressant Use at Baseline			
Yes, n / N (%)	10/13 (76.9)	14/16 (87.5)	0.3062
No, n / N (%)	52/62 (83.9)	55/60 (91.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-int.sas:t-sf36-mh-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	16/21 (76.2)	13/13 (100.0)	0.7956(a)
25-29.9, n / N (%)	17/20 (85.0)	18/21 (85.7)	0.9448(b)
>=30, n / N (%)	29/34 (85.3)	38/42 (90.5)	0.8100(c)
Onset of PPD			
3rd Trimester, n / N (%)	24/32 (75.0)	31/32 (96.9)	0.4544
Postpartum, n / N (%)	38/43 (88.4)	38/44 (86.4)	
Family History of PPD			
Yes, n / N (%)	9/10 (90.0)	8/10 (80.0)	0.1849
No/Unknown, n / N (%)	53/65 (81.5)	61/66 (92.4)	
History of PPD			
1st Episode, n / N (%)	51/59 (86.4)	59/66 (89.4)	0.1486
Recurrent Episode, n / N (%)	11/16 (68.8)	10/10 (100.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	6/8 (75.0)	9/10 (90.0)	NA
>=20, n / N (%)	56/67 (83.6)	60/66 (90.9)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-int.sas:t-sf36-mh-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.10.2.2 .2 .2 Subgruppenanalysen

2.10.2.2 .2 .2 .1 Alter

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	22 (88.0)	17 (100.0)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	42.0 (15.0, NE)	15.0 (15.0 , 16.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.443
95% CI for the HR		(0.7550 , 2.7568)
p-value for the HR		0.2673

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	40 (80.0)	52 (88.1)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 14.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (15.0, NE)	45.0 (15.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.969
95% CI for the HR		(0.6398 , 1.4686)
p-value for the HR		0.8831

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

2.10.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	20 (90.9)	26 (86.7)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (3.0 , 15.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	15.0 (15.0 , 45.0)	44.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.823
95% CI for the HR		(0.4483 , 1.5098)
p-value for the HR		0.5287

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	42 (79.2)	43 (93.5)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	43.0 (15.0, NE)	43.0 (15.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.100
95% CI for the HR		(0.7182 , 1.6856)
p-value for the HR		0.6606

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

2.10.2.2 .2 .2 .3 Abstammung

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	26 (81.3)	30 (96.8)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	43.0 (15.0, NE)	18.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.082
95% CI for the HR		(0.6355 , 1.8406)
p-value for the HR		0.7726

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	33 (82.5)	38 (86.4)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	29.5 (15.0, NE)	44.0 (15.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.989
95% CI for the HR		(0.6178 , 1.5837)
p-value for the HR		0.9638

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

2.10.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	10 (76.9)	14 (87.5)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (3.0 , 45.0)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	15.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.363
95% CI for the HR		(0.5953 , 3.1189)
p-value for the HR		0.4640

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 2 of 2

Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	52 (83.9)	55 (91.7)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	15.0 (15.0 , 45.0)	43.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.937
95% CI for the HR		(0.6402 , 1.3714)
p-value for the HR		0.7377

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

2.10.2.2 .2 .2 .5 BMI

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	16 (76.2)	13 (100.0)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (4.0 , 17.0)
75th percentile - Q3 (95% CI)	30.0 (15.0, NE)	17.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.080
95% CI for the HR		(0.4921 , 2.3687)
p-value for the HR		0.8485

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	17 (85.0)	18 (85.7)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (3.0 , 15.0)	15.0 (4.0 , 46.0)
75th percentile - Q3 (95% CI)	29.0 (15.0, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.989
95% CI for the HR		(0.5073 , 1.9292)
p-value for the HR		0.9747

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	29 (85.3)	38 (90.5)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 14.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (3.0 , 15.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	42.0 (15.0 , 45.0)	16.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.043
95% CI for the HR		(0.6367 , 1.7075)
p-value for the HR		0.8682

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

2.10.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	24 (75.0)	31 (96.9)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	3.5 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (3.0 , 15.0)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	43.0 (15.0, NE)	16.5 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.264
95% CI for the HR		(0.7332 , 2.1800)
p-value for the HR		0.3989

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	38 (88.4)	38 (86.4)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 15.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (15.0 , 16.0)
75th percentile - Q3 (95% CI)	16.0 (15.0 , 45.0)	43.0 (15.0 , 47.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.941
95% CI for the HR		(0.5972 , 1.4827)
p-value for the HR		0.7932

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

2.10.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	9 (90.0)	8 (80.0)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	15.0 (3.0 , 15.0)
50th percentile - median (95% CI)	3.5 (3.0 , 15.0)	15.0 (3.0, NE)
75th percentile - Q3 (95% CI)	15.0 (3.0, NE)	47.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.591
95% CI for the HR		(0.1944 , 1.7976)
p-value for the HR		0.3542

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	53 (81.5)	61 (92.4)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.5 (3.0 , 14.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (NE, NE)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	43.0 (15.0 , 47.0)	18.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.098
95% CI for the HR		(0.7585 , 1.5907)
p-value for the HR		0.6193

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

2.10.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	51 (86.4)	59 (89.4)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0 , 15.0)	15.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (15.0 , 45.0)	43.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.887
95% CI for the HR		(0.6071 , 1.2954)
p-value for the HR		0.5343

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	11 (68.8)	10 (100.0)
Time to first Mental Health Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (3.0 , 47.0)	15.0 (3.0 , 47.0)
75th percentile - Q3 (95% CI)	47.0 (15.0, NE)	47.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.035
95% CI for the HR		(0.9410 , 9.7890)
p-value for the HR		0.0631

NOTE 1: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

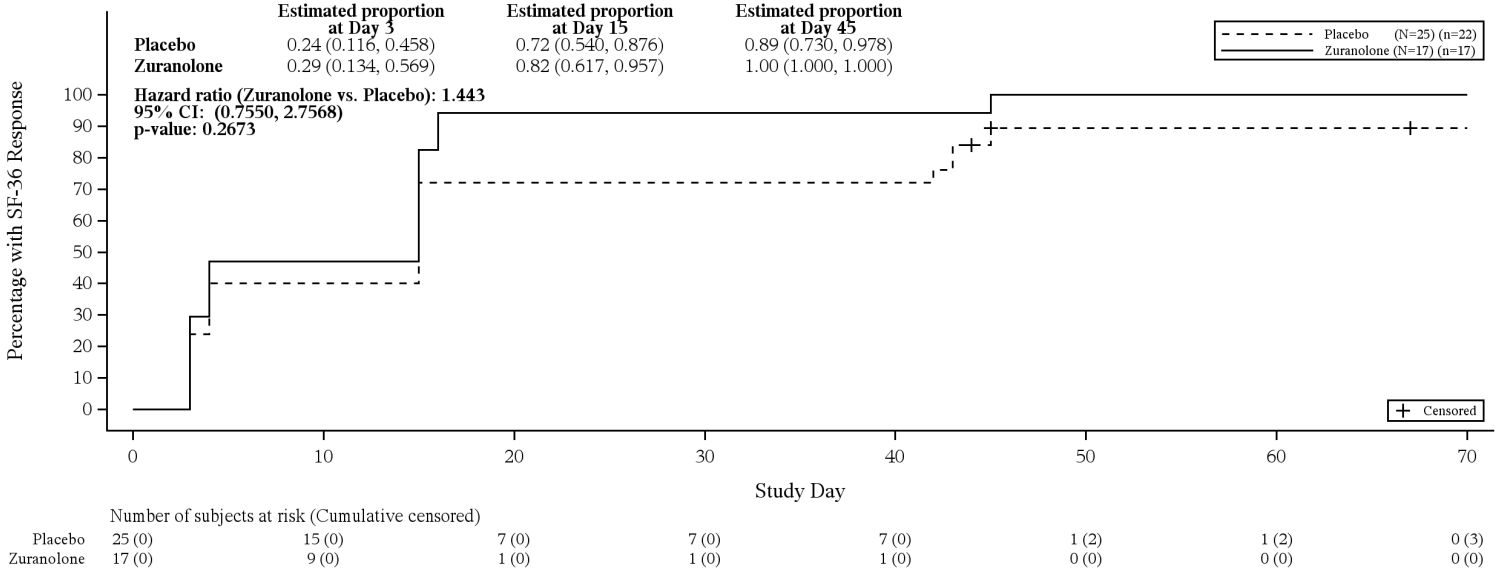
Source: biib125/v_a/germany_amnog/t-sf36-mh-resp15-tte-201-by.sas:t-sf36-mh-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

2.10.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

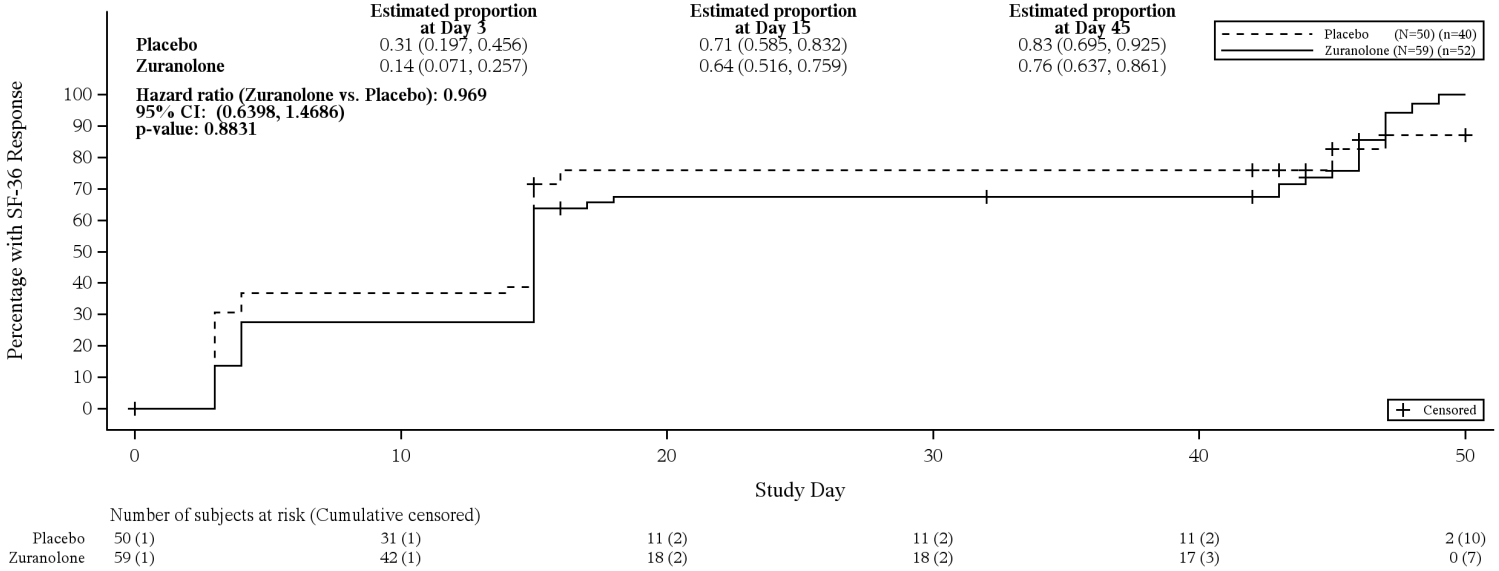
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

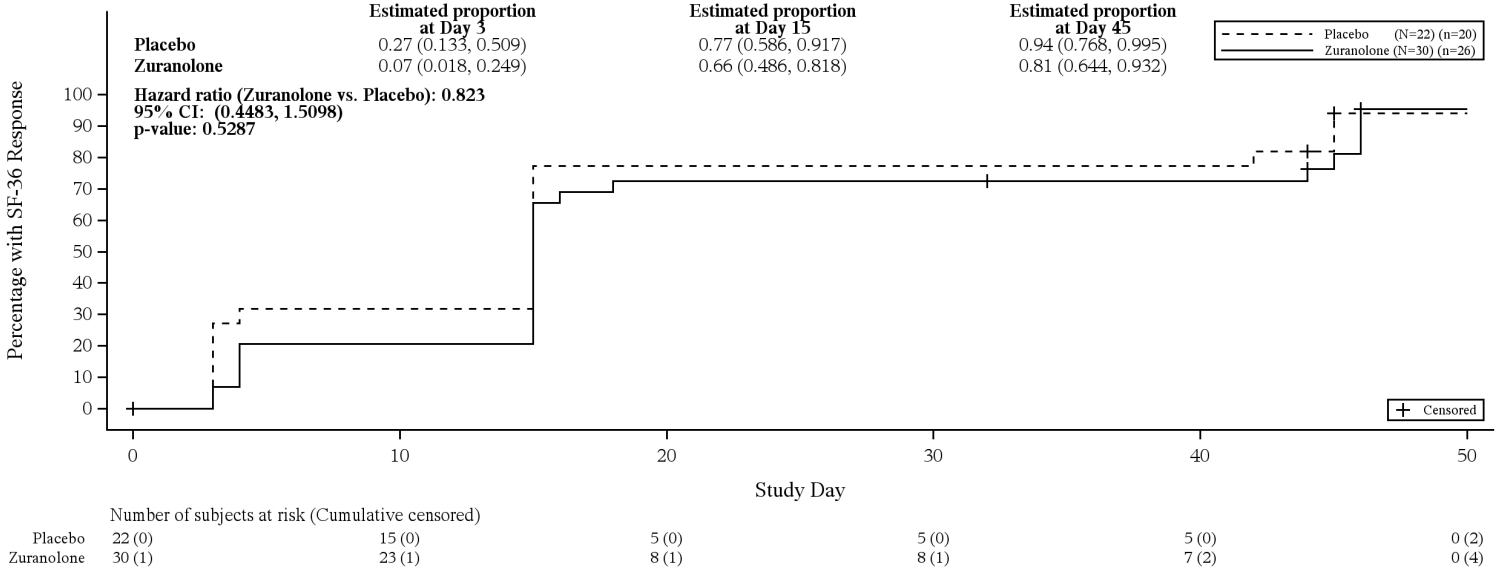
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	15 (0)	5 (0)	5 (0)	5 (0)	0 (2)
Zuranolone	30 (1)	23 (1)	8 (1)	8 (1)	7 (2)	0 (4)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

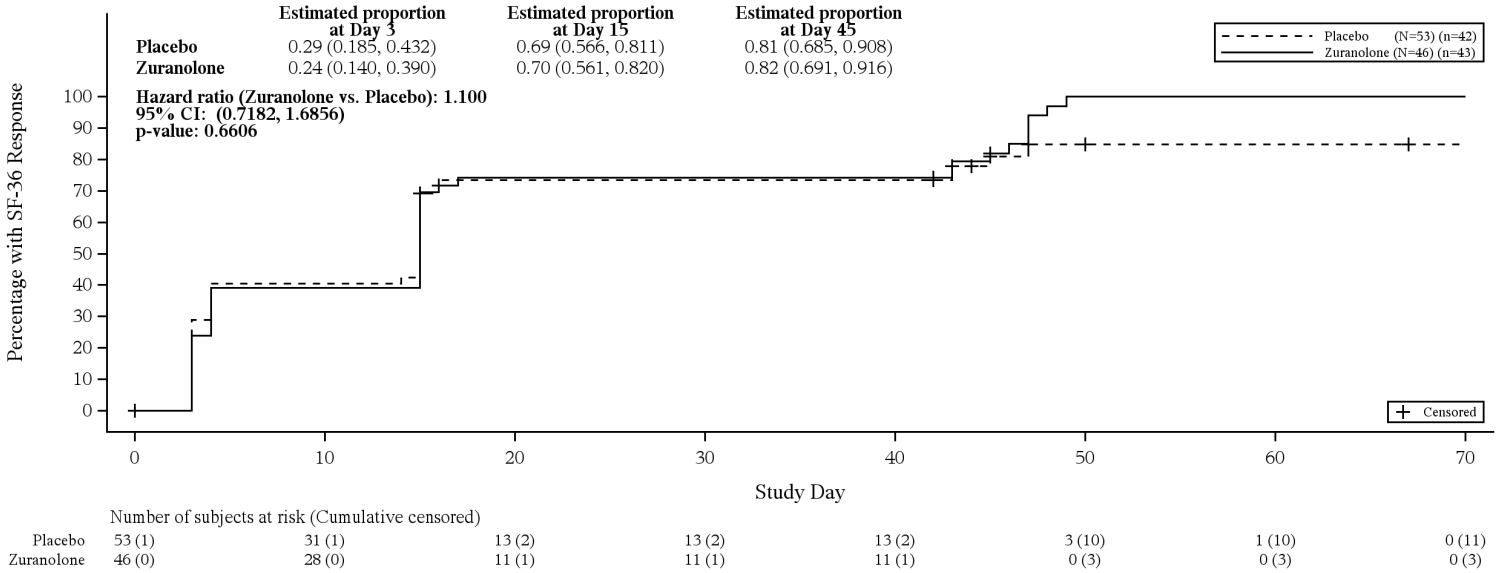
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

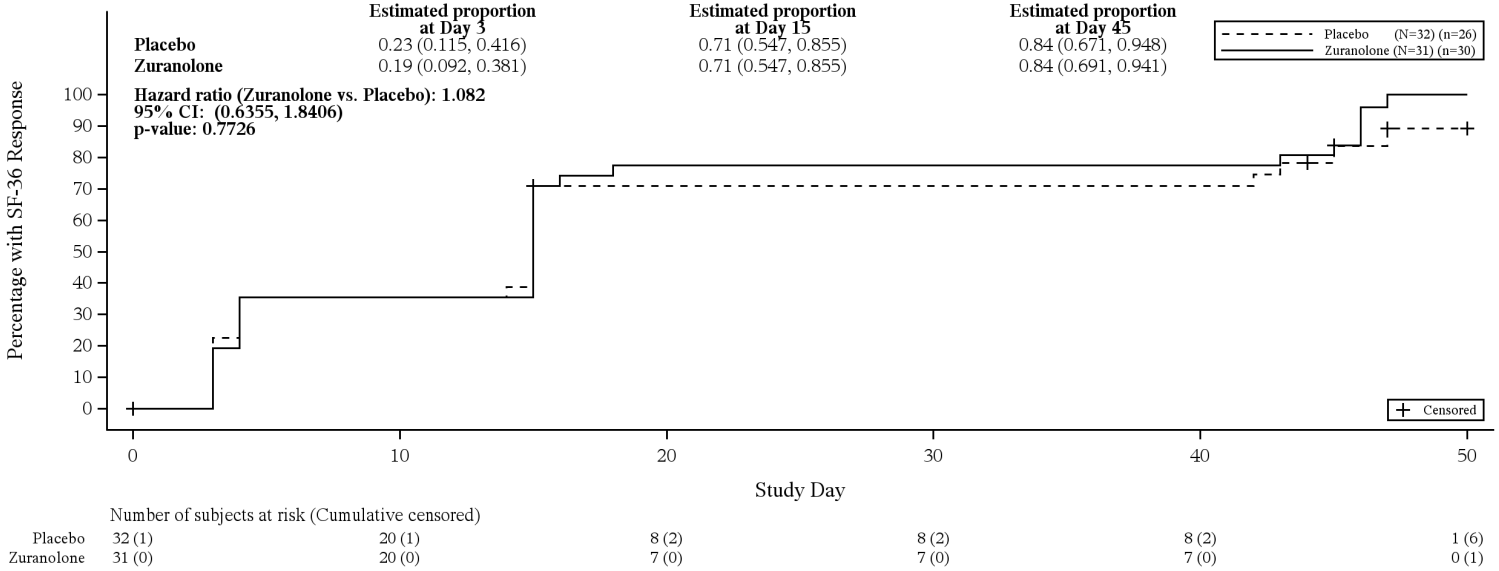
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

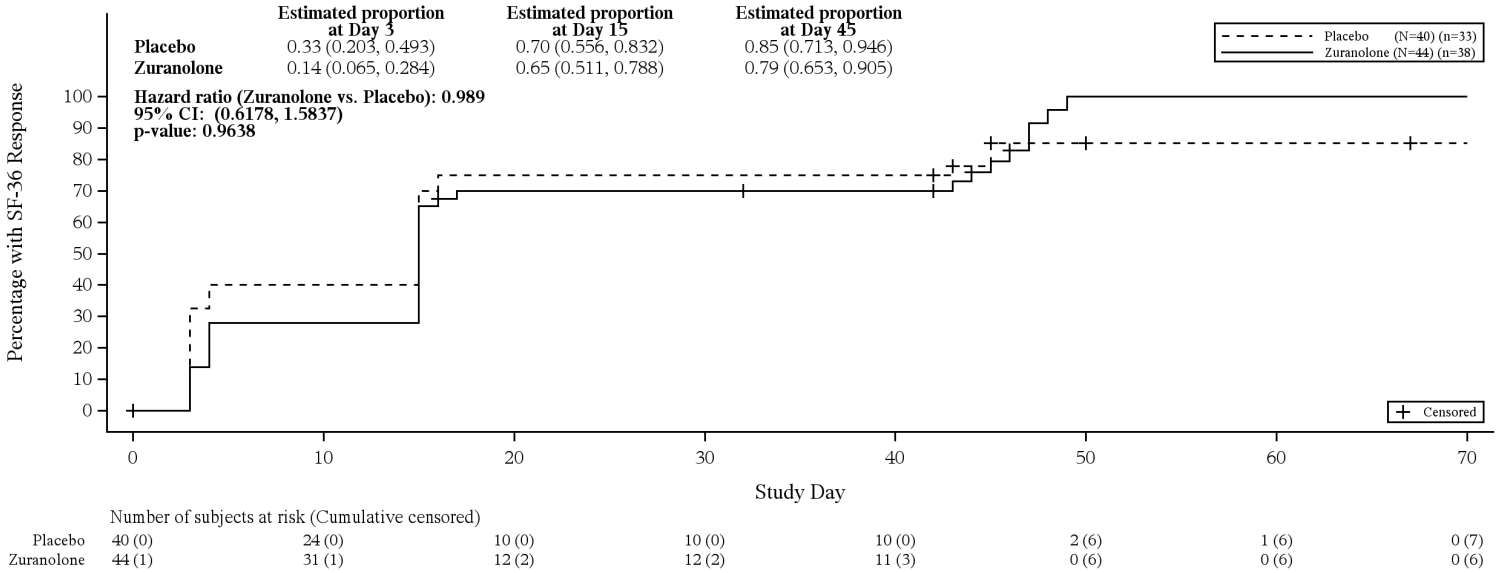
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

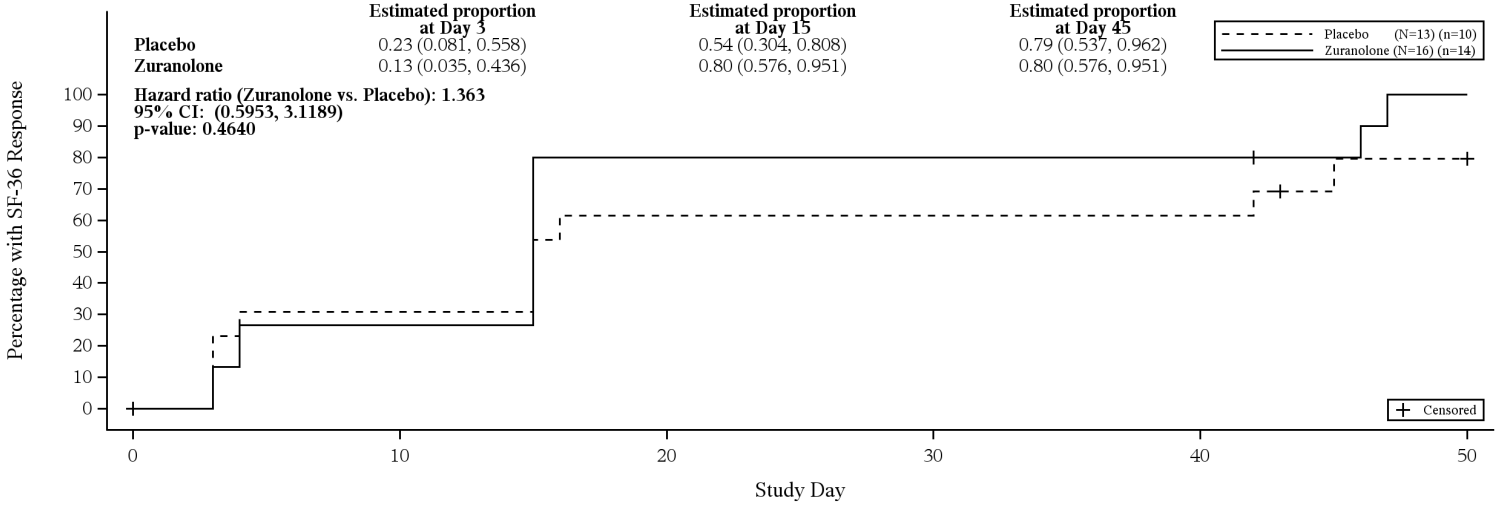
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	13 (0)	9 (0)	5 (0)	5 (0)	5 (0)	2 (3)
Zuranolone	16 (1)	11 (1)	3 (1)	3 (1)	3 (1)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

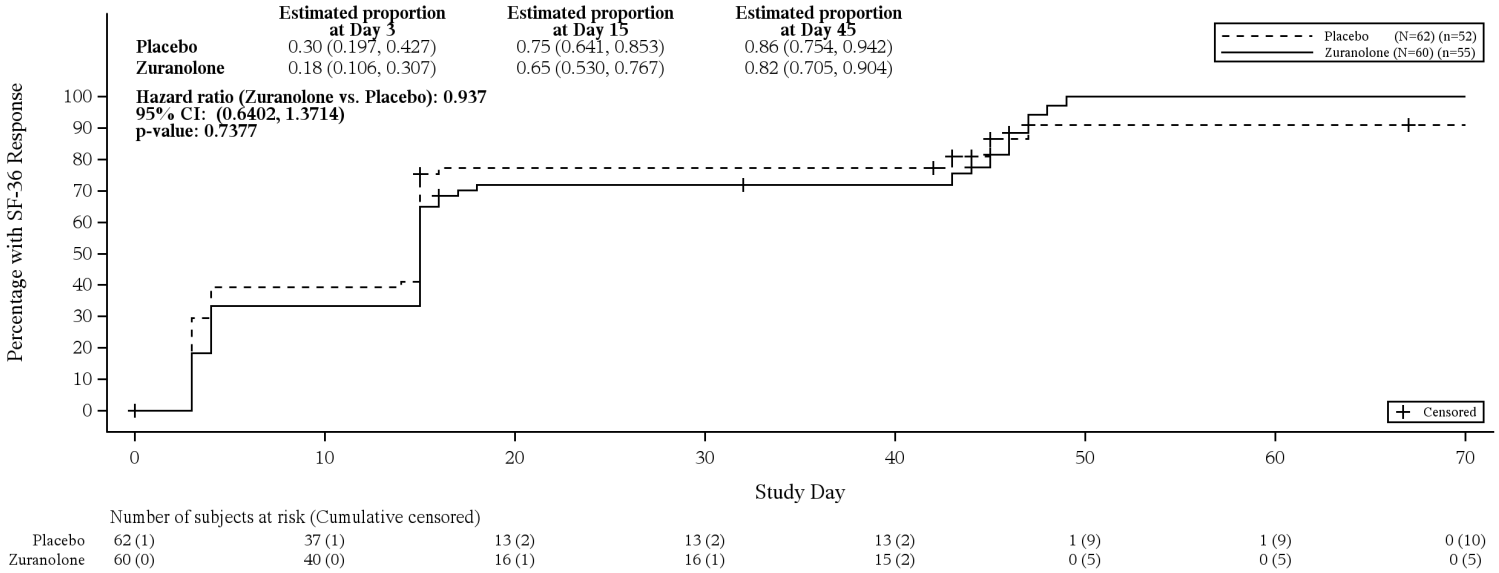
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

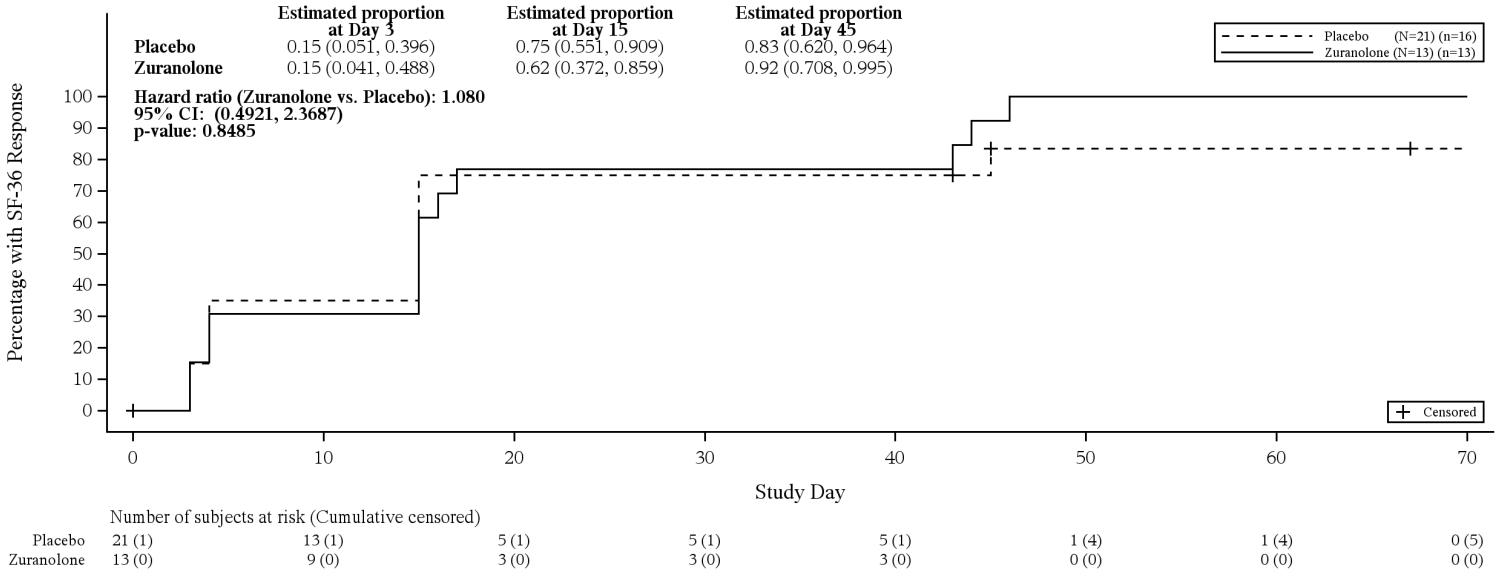
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

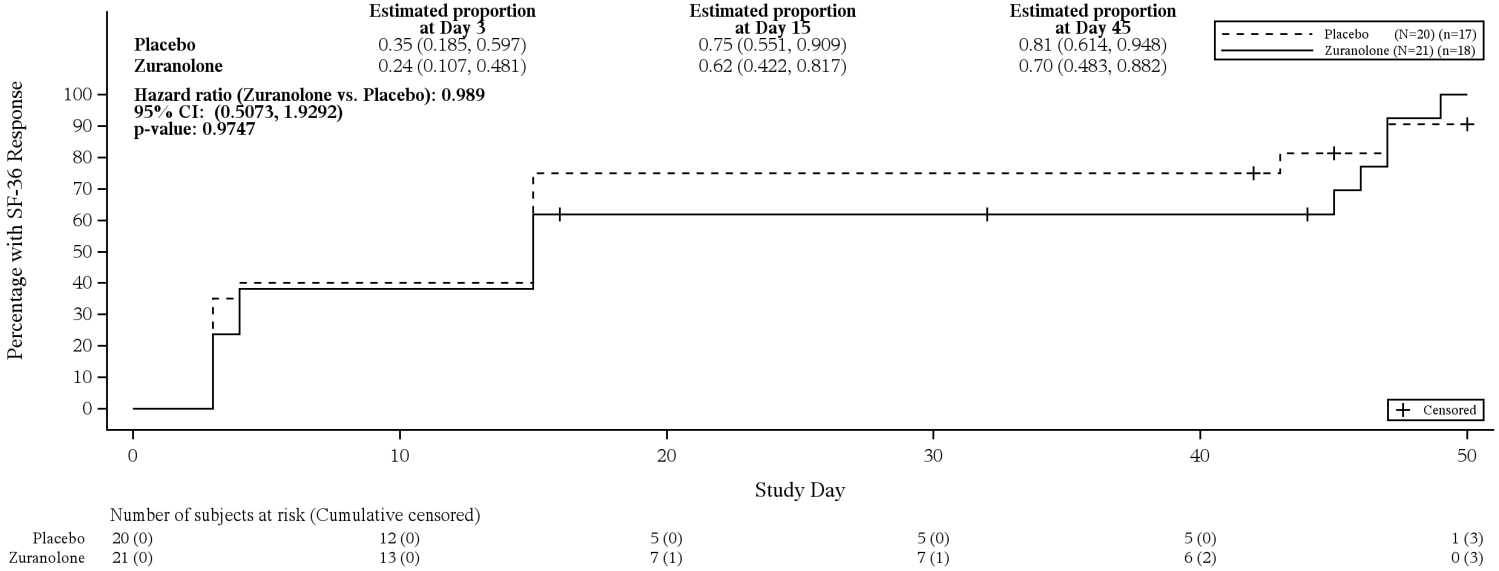
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Number of subjects at risk (Cumulative censored)

Placebo	20 (0)	12 (0)	5 (0)	5 (0)	5 (0)	1 (3)
Zuranolone	21 (0)	13 (0)	7 (1)	7 (1)	6 (2)	0 (3)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

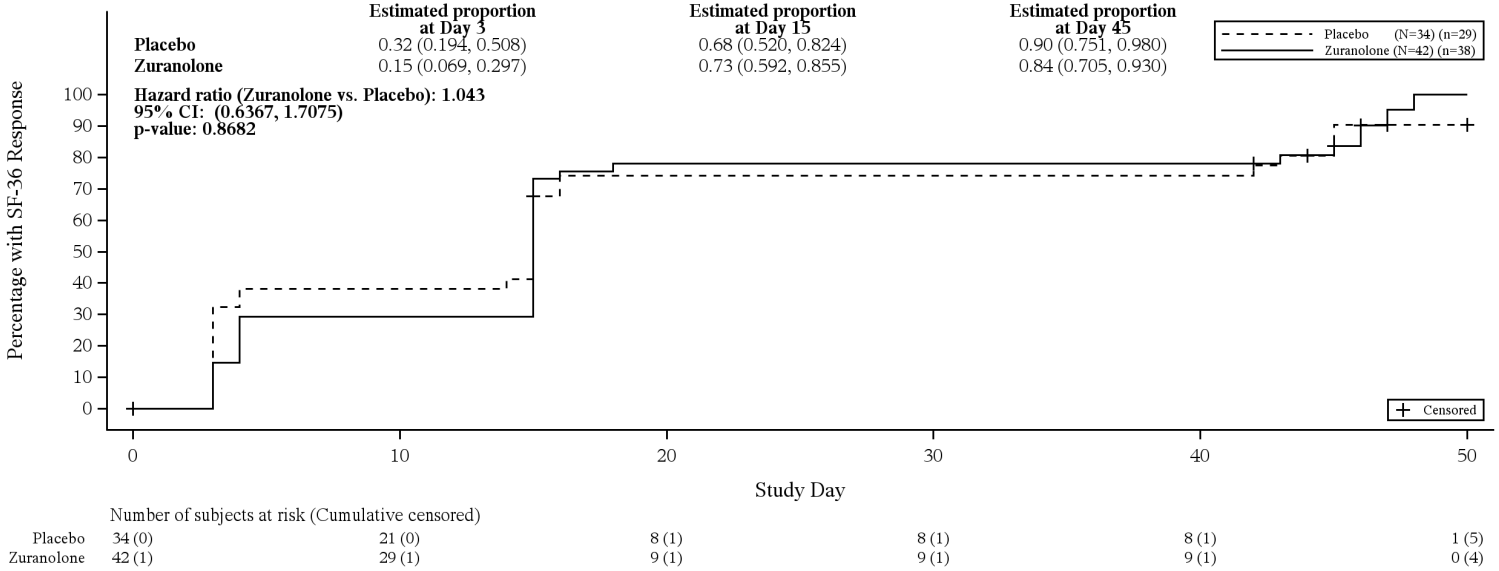
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

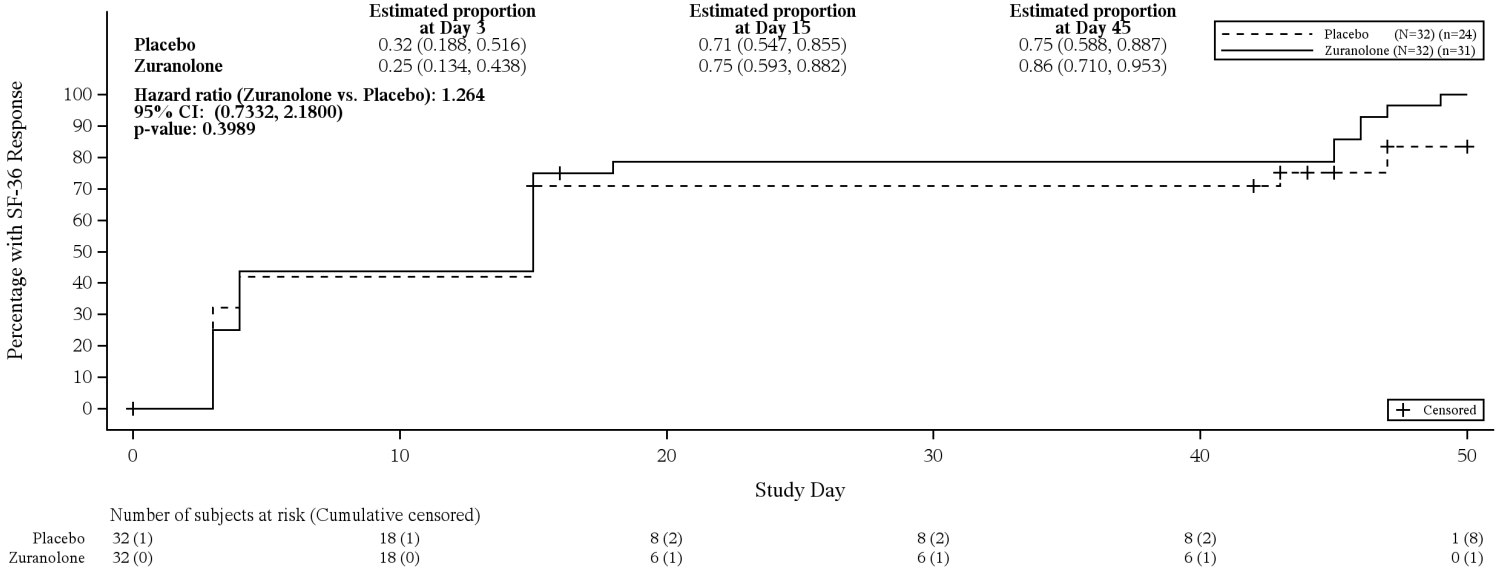
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

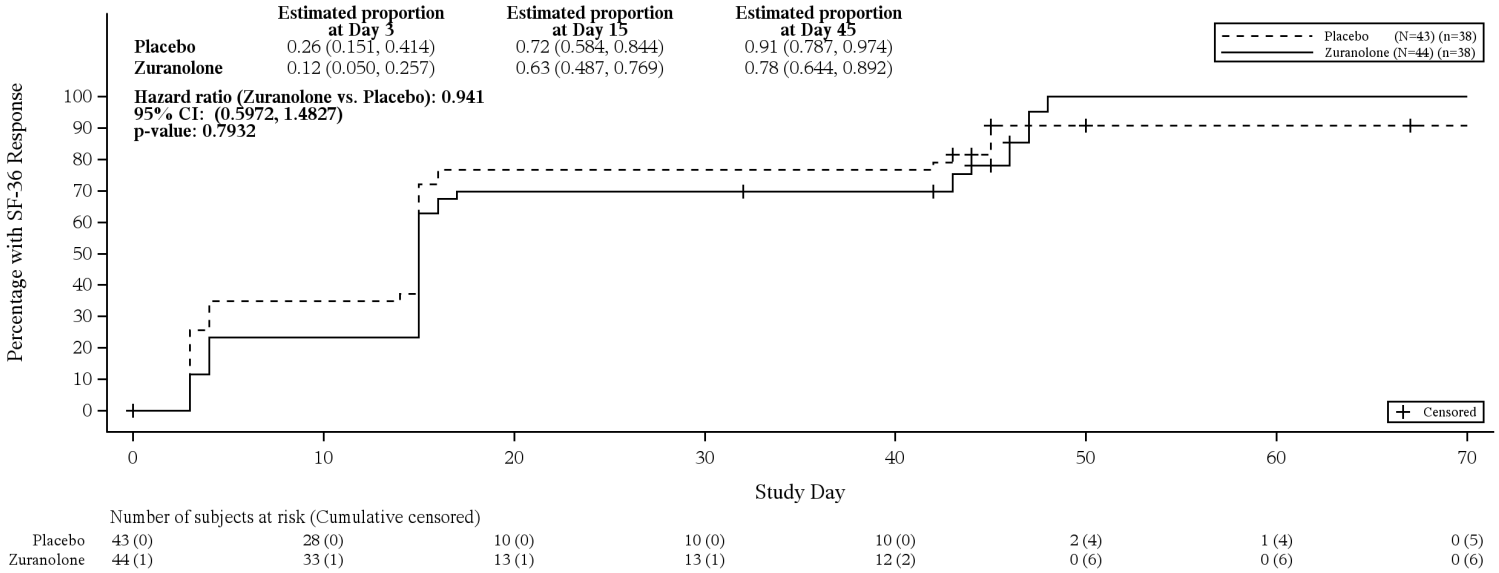
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

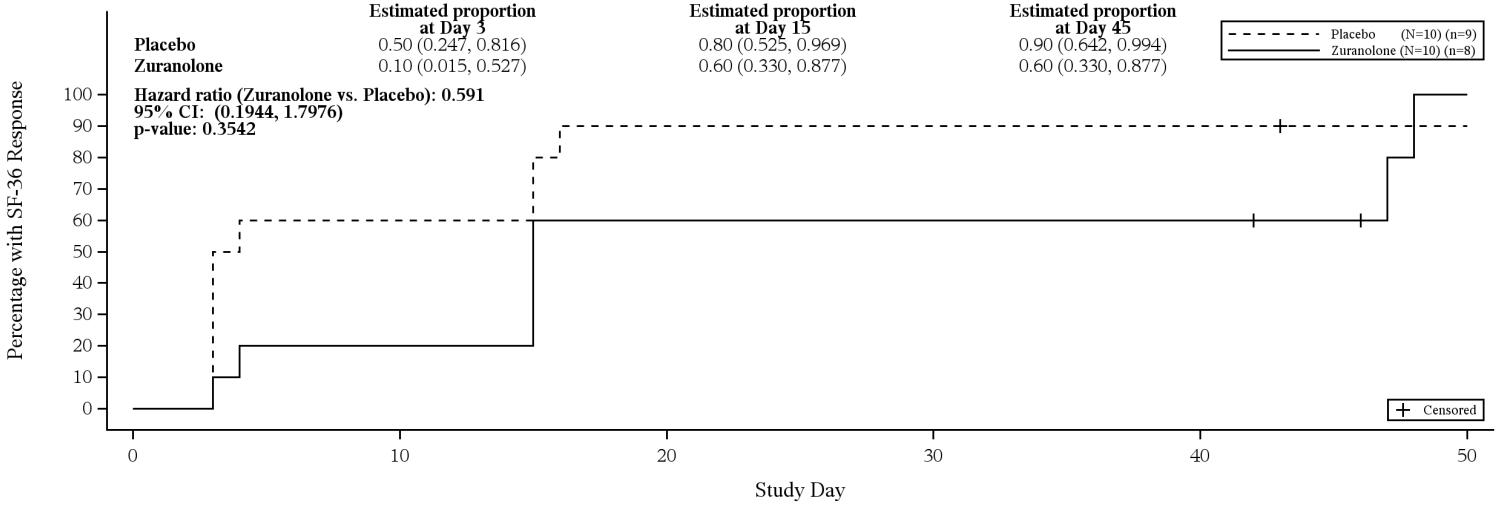
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Number of subjects at risk (Cumulative censored)

Placebo	10 (0)	4 (0)	1 (0)	1 (0)	1 (0)	0 (1)
Zuranolone	10 (0)	8 (0)	4 (0)	4 (0)	4 (0)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

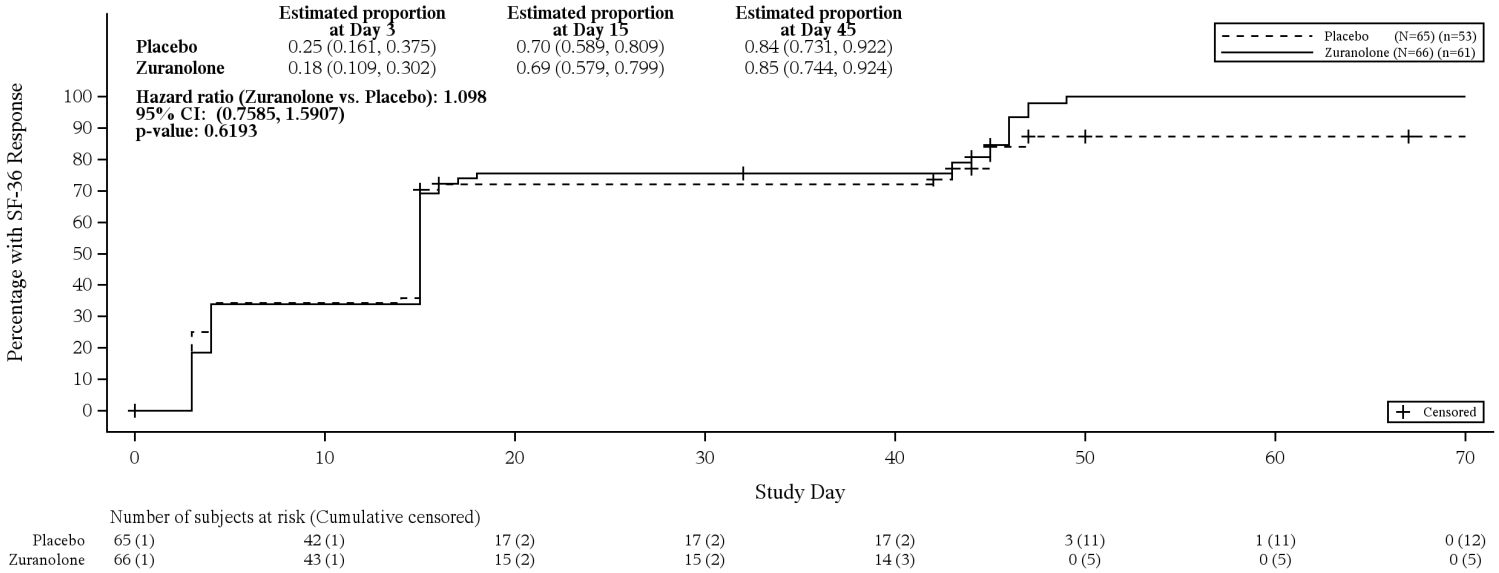
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

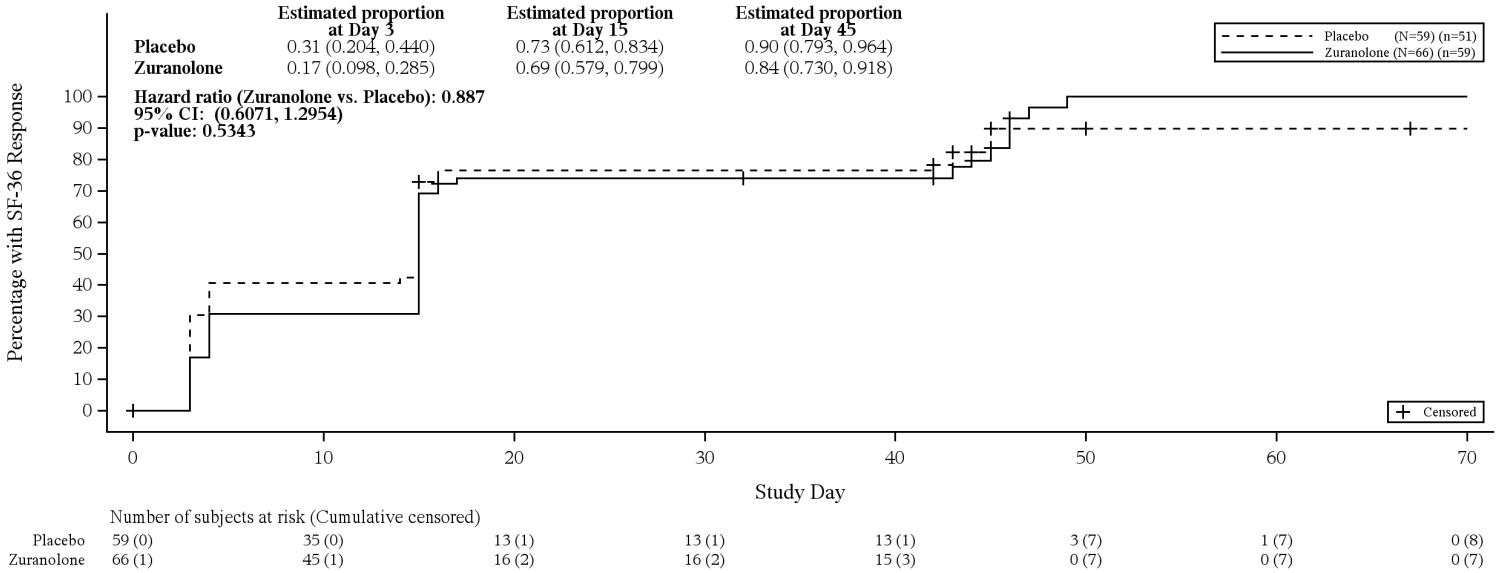
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

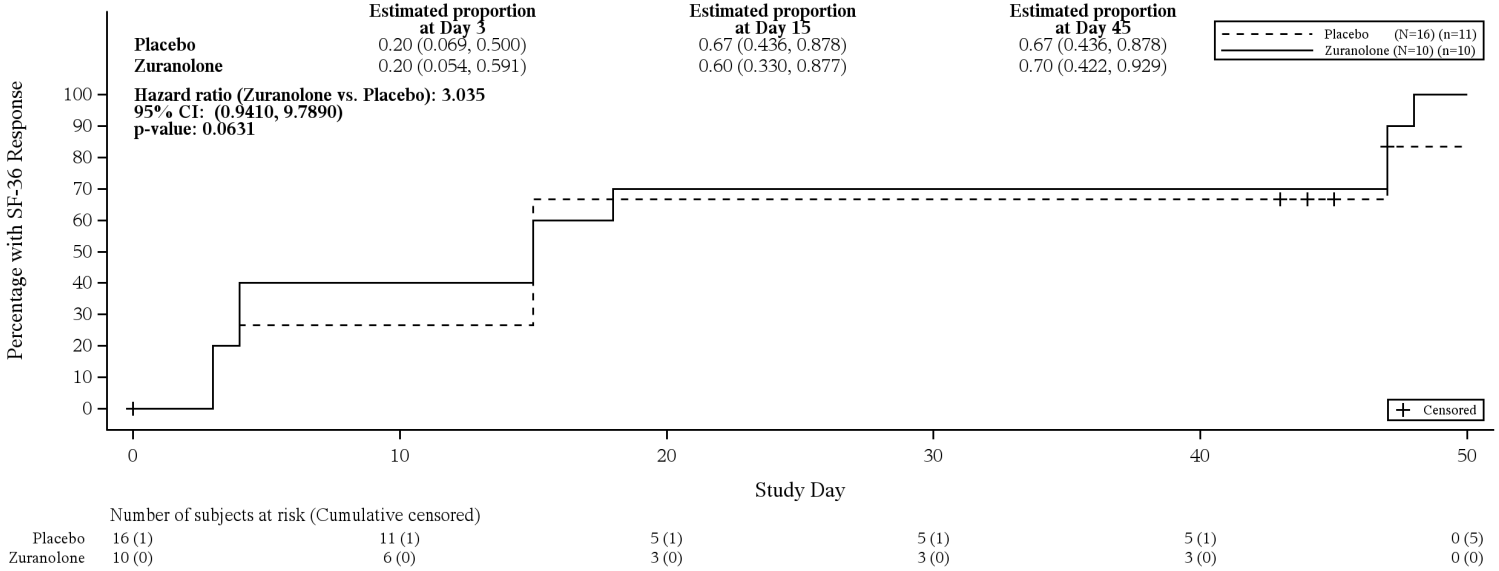
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: SF-36 subscale score (for the respective parameter) response is defined as 15 points (15% of total scale range 0-100) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-sf36-mh-resp15-tte-201-by.sas:f-sf36-mh-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

2.10.3 Verschlechterung

2.10.3.1 Responder-Analysen

2.10.3.1 .1 ITT-Population

Summary of Short-Form 36 (SF-36) Mental Health Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 15		
Number of subjects with worsening, n (%) [2]	2 (2.7)	1 (1.3)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.471
95% CI for the RR		(0.041, 5.374)
p-value for RR		0.5443
OR - Odds Ratio (Zuranolone vs. Placebo)		0.447
95% CI for the OR		(0.035, 5.702)
p-value for OR		0.5350
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.
[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a SF-36 Mental Health subscale score worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-sf36-mh-wors15-201-ovr.sas:t-sf36-mh-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 2

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	5 (6.7)	4 (5.3)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.753
95% CI for the RR		(0.225, 2.518)
p-value for RR		0.6454
OR - Odds Ratio (Zuranolone vs. Placebo)		0.680
95% CI for the OR		(0.174, 2.660)
p-value for OR		0.5792
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline SF-36 Mental Health subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing SF-36 Mental Health subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 Mental Health subscale score worsening (15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-sf36-mh-wors15-201-ovr.sas:t-sf36-mh-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.10.3.1 .2 Subgruppen

2.10.3.1 .2 .1 Interaktionstest

Summary of Short-Form 36 (SF-36) Mental Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	2 (2.7)	1 (1.3)	
Number of subjects with response at Day 45, n (%)	5 (6.7)	4 (5.3)	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	1/25 (4.0)	0/17	
25 - 45, n / N (%)	1/50 (2.0)	1/59 (1.7)	
Day 45			
18 - 24, n / N (%)	2/25 (8.0)	0/17	
25 - 45, n / N (%)	3/50 (6.0)	4/59 (6.8)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-wors15-201-int.sas:t-sf36-mh-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	1/22 (4.5)	0/30	
>=28, n / N (%)	1/53 (1.9)	1/46 (2.2)	
Day 45			
<28, n / N (%)	1/22 (4.5)	2/30 (6.7)	
>=28, n / N (%)	4/53 (7.5)	2/46 (4.3)	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	1/32 (3.1)	0/31	
White, n / N (%)	1/40 (2.5)	1/44 (2.3)	
Day 45			
Black or African American, n / N (%)	3/32 (9.4)	1/31 (3.2)	
White, n / N (%)	2/40 (5.0)	3/44 (6.8)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-wors15-201-int.sas:t-sf36-mh-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	1/13 (7.7)	0/16	
No, n / N (%)	1/62 (1.6)	1/60 (1.7)	
Day 45			
Yes, n / N (%)	0/13	1/16 (6.3)	
No, n / N (%)	5/62 (8.1)	3/60 (5.0)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-wors15-201-int.sas:t-sf36-mh-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 4 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	1/21 (4.8)	0/13	
25-29.9, n / N (%)	1/20 (5.0)	1/21 (4.8)	
>=30, n / N (%)	0/34	0/42	
Day 45			
<=24.9, n / N (%)	1/21 (4.8)	0/13	
25-29.9, n / N (%)	0/20	1/21 (4.8)	
>=30, n / N (%)	4/34 (11.8)	3/42 (7.1)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-wors15-201-int.sas:t-sf36-mh-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	1/32 (3.1)	0/32	
Postpartum, n / N (%)	1/43 (2.3)	1/44 (2.3)	
Day 45			
3rd Trimester, n / N (%)	4/32 (12.5)	0/32	
Postpartum, n / N (%)	1/43 (2.3)	4/44 (9.1)	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	2/65 (3.1)	1/66 (1.5)	
Day 45			
Yes, n / N (%)	1/10 (10.0)	2/10 (20.0)	
No/Unknown, n / N (%)	4/65 (6.2)	2/66 (3.0)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-wors15-201-int.sas:t-sf36-mh-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Short-Form 36 (SF-36) Mental Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 6 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	1/59 (1.7)	0/66	
Recurrent Episode, n / N (%)	1/16 (6.3)	1/10 (10.0)	
Day 45			
1st Episode, n / N (%)	3/59 (5.1)	4/66 (6.1)	
Recurrent Episode, n / N (%)	2/16 (12.5)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	1/8 (12.5)	1/10 (10.0)	
>=20, n / N (%)	1/67 (1.5)	0/66	
Day 45			
<20, n / N (%)	1/8 (12.5)	1/10 (10.0)	
>=20, n / N (%)	4/67 (6.0)	3/66 (4.5)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-wors15-201-int.sas:t-sf36-mh-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

2.10.3.1 .2 .2 Subgruppenanalysen

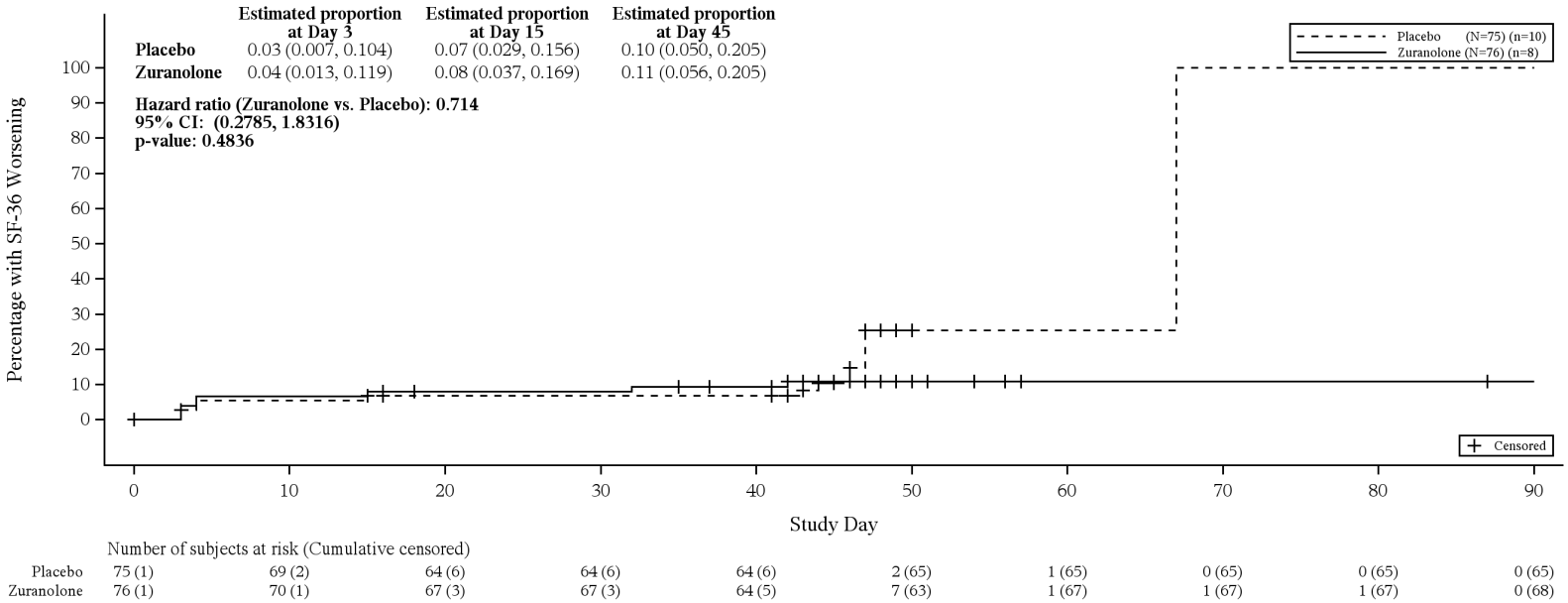
Nicht zutreffend.

2.10.3.2 TTE-Analysen

2.10.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Short-Form 36 (SF-36) Mental Health Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.
Source: biib125/v_a/amnog_kmplots/f-sf36-mh-wors15-tte-201-ovr.sas:f-sf36-mh-wors15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	10 (13.3)	8 (10.5)
Time to first Mental Health Subscale worsening (days) [3]		
25th percentile - Q1 (95% CI)	47.0 (46.0, NE)	NE (NE, NE)
50th percentile - median (95% CI)	67.0 (47.0, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	67.0 (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.714
95% CI for the HR		(0.2785 , 1.8316)
p-value for the HR		0.4836

NOTE 1: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing SF-36 subscale score (for the respective parameter) at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a SF-36 subscale score (for the respective parameter) worsening. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), and treatment.

Source: biib125/v_a/germany_amnog/t-sf36-mh-wors15-tte-201-ovr.sas:t-sf36-mh-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

2.10.3.2 .2 Subgruppen

2.10.3.2 .2 .1 Interaktionstest

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	10 (13.3)	8 (10.5)	
Age Group (years)			
18 - 24, n / N (%)	3/25 (12.0)	0/17	NA
25 - 45, n / N (%)	7/50 (14.0)	8/59 (13.6)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	4/22 (18.2)	4/30 (13.3)	NA
>=28, n / N (%)	6/53 (11.3)	4/46 (8.7)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	4/32 (12.5)	4/31 (12.9)	NA
White, n / N (%)	6/40 (15.0)	4/44 (9.1)	
Antidepressant Use at Baseline			
Yes, n / N (%)	3/13 (23.1)	1/16 (6.3)	NA
No, n / N (%)	7/62 (11.3)	7/60 (11.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-wors15-tte-201-int.sas:t-sf36-mh-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Short-Form 36 (SF-36) Mental Health Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	3/21 (14.3)	1/13 (7.7)	NA(a)
25-29.9, n / N (%)	1/20 (5.0)	2/21 (9.5)	NA(b)
>=30, n / N (%)	6/34 (17.6)	5/42 (11.9)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	6/32 (18.8)	2/32 (6.3)	NA
Postpartum, n / N (%)	4/43 (9.3)	6/44 (13.6)	
Family History of PPD			
Yes, n / N (%)	1/10 (10.0)	2/10 (20.0)	NA
No/Unknown, n / N (%)	9/65 (13.8)	6/66 (9.1)	
History of PPD			
1st Episode, n / N (%)	6/59 (10.2)	7/66 (10.6)	NA
Recurrent Episode, n / N (%)	4/16 (25.0)	1/10 (10.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	3/8 (37.5)	3/10 (30.0)	NA
>=20, n / N (%)	7/67 (10.4)	5/66 (7.6)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline SF-36 subscale score (for the respective parameter), treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: SF-36 subscale score (for the respective parameter) worsening is defined as 15 points (15% of total scale range 0-100) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sf36-mh-wors15-tte-201-int.sas:t-sf36-mh-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

2.10.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

2.10.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

3 BIMF

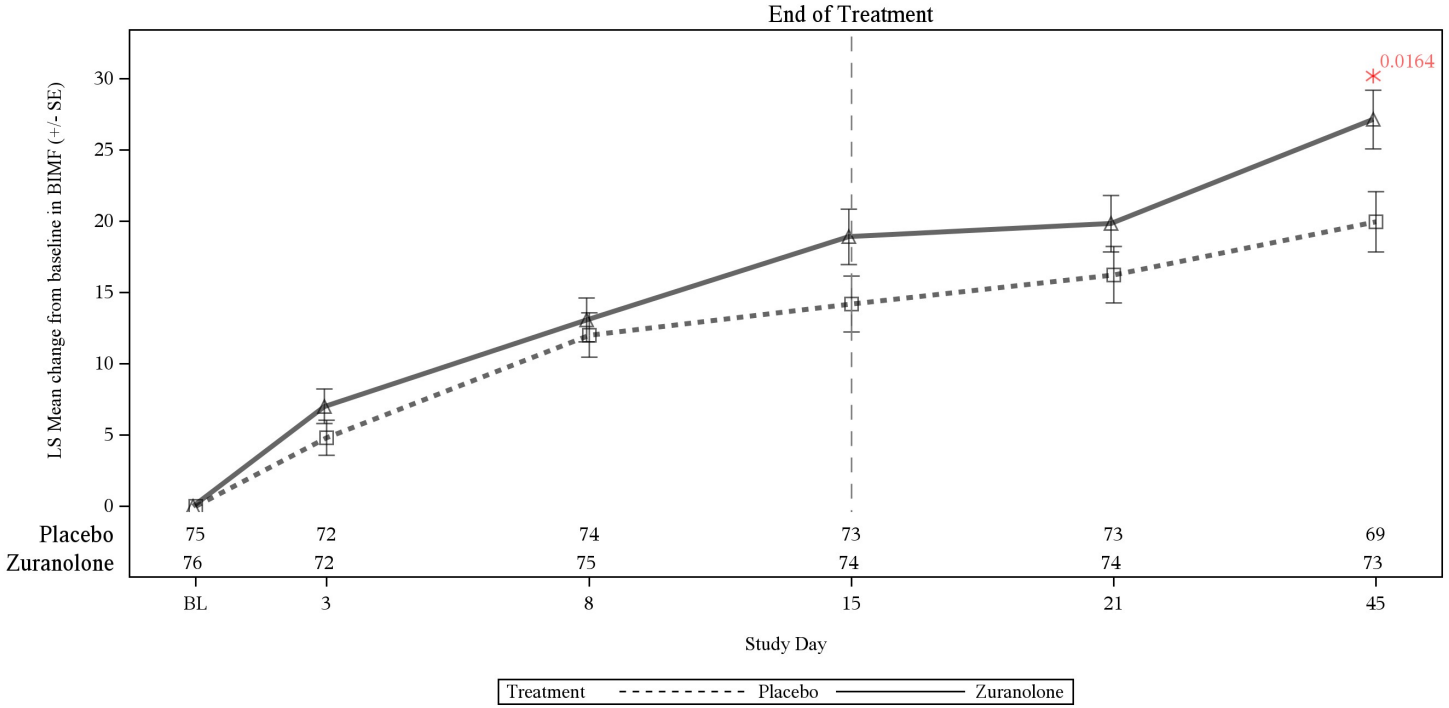
3.1 BIMF Gesamtwert

3.1.1 MMRM

3.1.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-ovr.sas:f-bimf-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score: 217-PPD-201B - ITT population

Page: 1 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 3		
n	72	72
LS Mean (SE)	4.81 (1.222)	7.02 (1.218)
95% CI for the LS Mean	2.40, 7.23	4.62, 9.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.21 (1.731)
95% CI for the LS Mean		-1.21, 5.63
p-value		0.2038
Hedges' g (Zuranolone vs. Placebo)		0.212
95% CI for Hedges' g		-0.1159, 0.5392
Day 8		
n	74	75
LS Mean (SE)	12.01 (1.552)	13.10 (1.538)
95% CI for the LS Mean	8.94, 15.07	10.06, 16.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.09 (2.190)
95% CI for the LS Mean		-3.24, 5.42
p-value		0.6183
Hedges' g (Zuranolone vs. Placebo)		0.081
95% CI for Hedges' g		-0.2399, 0.4027

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-ovr.sas:t-bimf-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score: 217-PPD-201B - ITT population

Page: 2 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	14.19 (1.972)	18.91 (1.953)
95% CI for the LS Mean	10.29, 18.09	15.05, 22.77
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.72 (2.779)
95% CI for the LS Mean		-0.77, 10.21
p-value		0.0917
Hedges' g (Zuranolone vs. Placebo)		0.279
95% CI for Hedges' g		-0.0462, 0.6036
Day 21		
n	73	74
LS Mean (SE)	16.25 (1.987)	19.83 (1.969)
95% CI for the LS Mean	12.32, 20.18	15.94, 23.73
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.58 (2.801)
95% CI for the LS Mean		-1.96, 9.12
p-value		0.2034
Hedges' g (Zuranolone vs. Placebo)		0.210
95% CI for Hedges' g		-0.1145, 0.5339

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-ovr.sas:t-bimf-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score: 217-PPD-201B - ITT population

Page: 3 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 45		
n	69	73
LS Mean (SE)	19.97 (2.103)	27.14 (2.067)
95% CI for the LS Mean	15.81, 24.13	23.05, 31.23
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.17 (2.952)
95% CI for the LS Mean		1.34, 13.01
p-value		0.0164
Hedges' g (Zuranolone vs. Placebo)		0.406
95% CI for Hedges' g		0.0734, 0.7383

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-ovr.sas:t-bimf-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.1.1.2 Subgruppen

3.1.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.8738
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.7586
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.3133
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.8672
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup interaction analysis.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-int.sas:t-bimf-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.5581(a)
25-29.9	20	21	0.6483(b)
>=30	34	42	0.2267(c)
Onset of PPD			
3rd Trimester	32	32	0.6997
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.1884
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.6003
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup interaction analysis.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-int.sas:t-bimf-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

3.1.1.2 .2 Subgruppenanalysen

3.1.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 3		
n	25	16
LS Mean (SE)	6.97 (2.093)	4.81 (2.607)
95% CI for the LS Mean	2.74, 11.21	-0.47, 10.08
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.17 (3.409)
95% CI for the LS Mean		-9.07, 4.73
p-value		0.5287
Hedges' g (Zuranolone vs. Placebo)		-0.200
95% CI for Hedges' g		-0.8286, 0.4293
Day 8		
n	25	17
LS Mean (SE)	11.89 (2.926)	12.25 (3.575)
95% CI for the LS Mean	5.96, 17.82	5.01, 19.49
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.35 (4.673)
95% CI for the LS Mean		-9.11, 9.81
p-value		0.9401
Hedges' g (Zuranolone vs. Placebo)		0.023
95% CI for Hedges' g		-0.5928, 0.6395

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	13.01 (3.389)	18.13 (4.133)
95% CI for the LS Mean	6.16, 19.87	9.78, 26.48
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.12 (5.390)
95% CI for the LS Mean		-5.77, 16.01
p-value		0.3482
Hedges' g (Zuranolone vs. Placebo)		0.293
95% CI for Hedges' g		-0.3266, 0.9121
Day 21		
n	25	16
LS Mean (SE)	15.57 (3.441)	21.84 (4.232)
95% CI for the LS Mean	8.61, 22.54	13.28, 30.40
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.27 (5.497)
95% CI for the LS Mean		-4.85, 17.38
p-value		0.2613
Hedges' g (Zuranolone vs. Placebo)		0.358
95% CI for Hedges' g		-0.2744, 0.9901

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 45		
n	25	16
LS Mean (SE)	18.49 (3.405)	26.04 (4.214)
95% CI for the LS Mean	11.58, 25.40	17.50, 34.58
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.55 (5.461)
95% CI for the LS Mean		-3.52, 18.62
p-value		0.1754
Hedges' g (Zuranolone vs. Placebo)		0.434
95% CI for Hedges' g		-0.2006, 1.0683

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 3		
n	47	56
LS Mean (SE)	3.54 (1.477)	7.80 (1.353)
95% CI for the LS Mean	0.61, 6.47	5.12, 10.49
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.26 (2.005)
95% CI for the LS Mean		0.28, 8.24
p-value		0.0361
Hedges' g (Zuranolone vs. Placebo)		0.417
95% CI for Hedges' g		0.0256, 0.8093
Day 8		
n	49	58
LS Mean (SE)	11.95 (1.893)	13.50 (1.734)
95% CI for the LS Mean	8.20, 15.71	10.05, 16.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.54 (2.569)
95% CI for the LS Mean		-3.55, 6.64
p-value		0.5494
Hedges' g (Zuranolone vs. Placebo)		0.116
95% CI for Hedges' g		-0.2649, 0.4964

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	14.70 (2.473)	19.28 (2.262)
95% CI for the LS Mean	9.80, 19.61	14.79, 23.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.58 (3.353)
95% CI for the LS Mean		-2.07, 11.23
p-value		0.1753
Hedges' g (Zuranolone vs. Placebo)		0.265
95% CI for Hedges' g		-0.1202, 0.6511
Day 21		
n	48	58
LS Mean (SE)	16.47 (2.480)	19.42 (2.264)
95% CI for the LS Mean	11.55, 21.39	14.92, 23.91
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.95 (3.360)
95% CI for the LS Mean		-3.72, 9.61
p-value		0.3827
Hedges' g (Zuranolone vs. Placebo)		0.170
95% CI for Hedges' g		-0.2133, 0.5530

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 45		
n	44	57
LS Mean (SE)	20.70 (2.713)	27.57 (2.441)
95% CI for the LS Mean	15.32, 26.08	22.72, 32.42
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.87 (3.651)
95% CI for the LS Mean		-0.38, 14.12
p-value		0.0629
Hedges' g (Zuranolone vs. Placebo)		0.375
95% CI for Hedges' g		-0.0219, 0.7715

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

3.1.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 3		
n	20	26
LS Mean (SE)	7.98 (2.304)	5.46 (1.977)
95% CI for the LS Mean	3.33, 12.63	1.47, 9.46
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.52 (3.141)
95% CI for the LS Mean		-8.86, 3.82
p-value		0.4266
Hedges' g (Zuranolone vs. Placebo)		-0.235
95% CI for Hedges' g		-0.8196, 0.3503
Day 8		
n	22	29
LS Mean (SE)	13.02 (2.814)	12.03 (2.443)
95% CI for the LS Mean	7.36, 18.68	7.13, 16.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.99 (3.803)
95% CI for the LS Mean		-8.62, 6.65
p-value		0.7963
Hedges' g (Zuranolone vs. Placebo)		-0.072
95% CI for Hedges' g		-0.6266, 0.4821

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	15.93 (3.631)	20.18 (3.153)
95% CI for the LS Mean	8.63, 23.23	13.85, 26.51
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.25 (4.868)
95% CI for the LS Mean		-5.52, 14.03
p-value		0.3867
Hedges' g (Zuranolone vs. Placebo)		0.245
95% CI for Hedges' g		-0.3156, 0.8053
Day 21		
n	22	28
LS Mean (SE)	19.20 (3.630)	18.45 (3.161)
95% CI for the LS Mean	11.89, 26.51	12.09, 24.81
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.75 (4.871)
95% CI for the LS Mean		-10.55, 9.05
p-value		0.8787
Hedges' g (Zuranolone vs. Placebo)		-0.043
95% CI for Hedges' g		-0.6015, 0.5154

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 45		
n	22	28
LS Mean (SE)	21.11 (3.978)	29.45 (3.475)
95% CI for the LS Mean	13.09, 29.13	22.45, 36.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.34 (5.335)
95% CI for the LS Mean		-2.41, 19.08
p-value		0.1252
Hedges' g (Zuranolone vs. Placebo)		0.438
95% CI for Hedges' g		-0.1268, 1.0032

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 3		
n	52	46
LS Mean (SE)	3.93 (1.478)	7.67 (1.573)
95% CI for the LS Mean	1.00, 6.87	4.54, 10.79
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.74 (2.161)
95% CI for the LS Mean		-0.56, 8.03
p-value		0.0872
Hedges' g (Zuranolone vs. Placebo)		0.347
95% CI for Hedges' g		-0.0525, 0.7469
Day 8		
n	52	46
LS Mean (SE)	11.80 (1.894)	13.47 (2.015)
95% CI for the LS Mean	8.03, 15.56	9.47, 17.47
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.67 (2.767)
95% CI for the LS Mean		-3.82, 7.17
p-value		0.5466
Hedges' g (Zuranolone vs. Placebo)		0.122
95% CI for Hedges' g		-0.2756, 0.5186

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	13.69 (2.366)	17.84 (2.511)
95% CI for the LS Mean	8.99, 18.39	12.85, 22.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.15 (3.452)
95% CI for the LS Mean		-2.70, 11.01
p-value		0.2321
Hedges' g (Zuranolone vs. Placebo)		0.243
95% CI for Hedges' g		-0.1574, 0.6426
Day 21		
n	51	46
LS Mean (SE)	15.24 (2.390)	20.36 (2.534)
95% CI for the LS Mean	10.49, 19.99	15.33, 25.40
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.12 (3.485)
95% CI for the LS Mean		-1.80, 12.05
p-value		0.1449
Hedges' g (Zuranolone vs. Placebo)		0.297
95% CI for Hedges' g		-0.1041, 0.6973

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 45		
n	47	45
LS Mean (SE)	19.63 (2.450)	25.42 (2.557)
95% CI for the LS Mean	14.77, 24.50	20.34, 30.51
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.79 (3.543)
95% CI for the LS Mean		-1.25, 12.83
p-value		0.1057
Hedges' g (Zuranolone vs. Placebo)		0.338
95% CI for Hedges' g		-0.0736, 0.7497

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

3.1.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 3		
n	31	29
LS Mean (SE)	4.51 (2.002)	5.59 (2.031)
95% CI for the LS Mean	0.49, 8.52	1.52, 9.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.08 (2.854)
95% CI for the LS Mean		-4.64, 6.80
p-value		0.7069
Hedges' g (Zuranolone vs. Placebo)		0.096
95% CI for Hedges' g		-0.4102, 0.6030
Day 8		
n	31	31
LS Mean (SE)	11.19 (2.366)	9.37 (2.368)
95% CI for the LS Mean	6.45, 15.92	4.63, 14.11
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.81 (3.351)
95% CI for the LS Mean		-8.52, 4.89
p-value		0.5904
Hedges' g (Zuranolone vs. Placebo)		-0.136
95% CI for Hedges' g		-0.6342, 0.3627

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	11.86 (2.606)	14.60 (2.607)
95% CI for the LS Mean	6.65, 17.08	9.38, 19.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.73 (3.689)
95% CI for the LS Mean		-4.65, 10.12
p-value		0.4614
Hedges' g (Zuranolone vs. Placebo)		0.186
95% CI for Hedges' g		-0.3130, 0.6849
Day 21		
n	31	30
LS Mean (SE)	13.86 (2.788)	14.77 (2.806)
95% CI for the LS Mean	8.28, 19.45	9.15, 20.38
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.90 (3.958)
95% CI for the LS Mean		-7.02, 8.83
p-value		0.8204
Hedges' g (Zuranolone vs. Placebo)		0.058
95% CI for Hedges' g		-0.4444, 0.5597

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 45		
n	30	30
LS Mean (SE)	19.20 (3.273)	22.81 (3.277)
95% CI for the LS Mean	12.64, 25.77	16.24, 29.39
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.61 (4.634)
95% CI for the LS Mean		-5.68, 12.90
p-value		0.4395
Hedges' g (Zuranolone vs. Placebo)		0.198
95% CI for Hedges' g		-0.3088, 0.7058

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 3		
n	39	42
LS Mean (SE)	5.35 (1.619)	7.88 (1.554)
95% CI for the LS Mean	2.13, 8.57	4.78, 10.97
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.53 (2.262)
95% CI for the LS Mean		-1.98, 7.03
p-value		0.2676
Hedges' g (Zuranolone vs. Placebo)		0.246
95% CI for Hedges' g		-0.1916, 0.6834
Day 8		
n	40	43
LS Mean (SE)	13.01 (2.175)	15.61 (2.086)
95% CI for the LS Mean	8.68, 17.35	11.46, 19.77
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.60 (3.027)
95% CI for the LS Mean		-3.43, 8.63
p-value		0.3933
Hedges' g (Zuranolone vs. Placebo)		0.187
95% CI for Hedges' g		-0.2446, 0.6183

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	15.70 (2.990)	21.99 (2.864)
95% CI for the LS Mean	9.74, 21.65	16.28, 27.69
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.29 (4.150)
95% CI for the LS Mean		-1.97, 14.55
p-value		0.1337
Hedges' g (Zuranolone vs. Placebo)		0.334
95% CI for Hedges' g		-0.1051, 0.7727
Day 21		
n	39	43
LS Mean (SE)	17.76 (2.833)	24.04 (2.707)
95% CI for the LS Mean	12.11, 23.41	18.65, 29.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.28 (3.929)
95% CI for the LS Mean		-1.55, 14.11
p-value		0.1140
Hedges' g (Zuranolone vs. Placebo)		0.350
95% CI for Hedges' g		-0.0863, 0.7871

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 45		
n	36	42
LS Mean (SE)	20.24 (2.936)	30.42 (2.781)
95% CI for the LS Mean	14.39, 26.09	24.87, 35.96
Difference (Zuranolone - Placebo)		
LS Mean (SE)		10.18 (4.054)
95% CI for the LS Mean		2.10, 18.25
p-value		0.0142
Hedges' g (Zuranolone vs. Placebo)		0.564
95% CI for Hedges' g		0.1106, 1.0184

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

3.1.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 3		
n	13	14
LS Mean (SE)	6.04 (2.225)	4.03 (2.154)
95% CI for the LS Mean	1.45, 10.64	-0.41, 8.47
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.01 (3.101)
95% CI for the LS Mean		-8.40, 4.38
p-value		0.5228
Hedges' g (Zuranolone vs. Placebo)		-0.242
95% CI for Hedges' g		-0.9998, 0.5155
Day 8		
n	13	16
LS Mean (SE)	14.51 (3.693)	15.72 (3.331)
95% CI for the LS Mean	6.91, 22.11	8.87, 22.57
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.21 (4.978)
95% CI for the LS Mean		-9.03, 11.46
p-value		0.8091
Hedges' g (Zuranolone vs. Placebo)		0.089
95% CI for Hedges' g		-0.6436, 0.8208

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	15.97 (4.925)	24.32 (4.506)
95% CI for the LS Mean	5.84, 26.10	15.07, 33.58
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.36 (6.679)
95% CI for the LS Mean		-5.37, 22.08
p-value		0.2220
Hedges' g (Zuranolone vs. Placebo)		0.460
95% CI for Hedges' g		-0.2921, 1.2127
Day 21		
n	12	15
LS Mean (SE)	16.97 (4.396)	23.48 (3.969)
95% CI for the LS Mean	7.93, 26.00	15.32, 31.65
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.52 (5.926)
95% CI for the LS Mean		-5.67, 18.70
p-value		0.2816
Hedges' g (Zuranolone vs. Placebo)		0.413
95% CI for Hedges' g		-0.3540, 1.1800

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 45		
n	11	15
LS Mean (SE)	18.29 (5.068)	27.87 (4.541)
95% CI for the LS Mean	7.83, 28.76	18.47, 37.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.58 (6.810)
95% CI for the LS Mean		-4.50, 23.65
p-value		0.1728
Hedges' g (Zuranolone vs. Placebo)		0.541
95% CI for Hedges' g		-0.2511, 1.3324

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 3		
n	59	58
LS Mean (SE)	4.50 (1.374)	7.39 (1.388)
95% CI for the LS Mean	1.78, 7.22	4.64, 10.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.89 (1.959)
95% CI for the LS Mean		-0.99, 6.77
p-value		0.1428
Hedges' g (Zuranolone vs. Placebo)		0.271
95% CI for Hedges' g		-0.0930, 0.6351
Day 8		
n	61	59
LS Mean (SE)	11.45 (1.725)	12.43 (1.747)
95% CI for the LS Mean	8.03, 14.87	8.97, 15.89
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.98 (2.460)
95% CI for the LS Mean		-3.89, 5.85
p-value		0.6907
Hedges' g (Zuranolone vs. Placebo)		0.072
95% CI for Hedges' g		-0.2856, 0.4304

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	13.77 (2.162)	17.55 (2.183)
95% CI for the LS Mean	9.49, 18.06	13.23, 21.87
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.77 (3.076)
95% CI for the LS Mean		-2.32, 9.87
p-value		0.2224
Hedges' g (Zuranolone vs. Placebo)		0.223
95% CI for Hedges' g		-0.1370, 0.5840
Day 21		
n	61	59
LS Mean (SE)	16.09 (2.246)	18.91 (2.271)
95% CI for the LS Mean	11.64, 20.54	14.41, 23.41
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.82 (3.198)
95% CI for the LS Mean		-3.51, 9.16
p-value		0.3796
Hedges' g (Zuranolone vs. Placebo)		0.160
95% CI for Hedges' g		-0.1984, 0.5185

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 45		
n	58	58
LS Mean (SE)	20.21 (2.338)	27.00 (2.352)
95% CI for the LS Mean	15.58, 24.85	22.34, 31.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.79 (3.320)
95% CI for the LS Mean		0.21, 13.37
p-value		0.0434
Hedges' g (Zuranolone vs. Placebo)		0.377
95% CI for Hedges' g		0.0099, 0.7442

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

3.1.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 3		
n	20	13
LS Mean (SE)	6.38 (2.256)	1.64 (2.812)
95% CI for the LS Mean	1.77, 10.99	-4.11, 7.39
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.74 (3.641)
95% CI for the LS Mean		-12.18, 2.71
p-value		0.2033
Hedges' g (Zuranolone vs. Placebo)		-0.452
95% CI for Hedges' g		-1.1590, 0.2544
Day 8		
n	20	13
LS Mean (SE)	12.73 (2.982)	9.57 (3.709)
95% CI for the LS Mean	6.64, 18.82	2.00, 17.13
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.17 (4.787)
95% CI for the LS Mean		-12.93, 6.60
p-value		0.5133
Hedges' g (Zuranolone vs. Placebo)		-0.230
95% CI for Hedges' g		-0.9303, 0.4706

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	13.53 (3.697)	16.64 (4.594)
95% CI for the LS Mean	5.98, 21.08	7.27, 26.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.11 (5.919)
95% CI for the LS Mean		-8.97, 15.19
p-value		0.6029
Hedges' g (Zuranolone vs. Placebo)		0.183
95% CI for Hedges' g		-0.5169, 0.8824
Day 21		
n	19	12
LS Mean (SE)	14.63 (3.679)	22.64 (4.605)
95% CI for the LS Mean	7.08, 22.17	13.21, 32.08
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.02 (5.915)
95% CI for the LS Mean		-4.10, 20.13
p-value		0.1861
Hedges' g (Zuranolone vs. Placebo)		0.487
95% CI for Hedges' g		-0.2460, 1.2195

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 45		
n	18	12
LS Mean (SE)	16.72 (4.640)	30.32 (5.725)
95% CI for the LS Mean	7.23, 26.21	18.60, 42.03
Difference (Zuranolone - Placebo)		
LS Mean (SE)		13.60 (7.385)
95% CI for the LS Mean		-1.51, 28.71
p-value		0.0760
Hedges' g (Zuranolone vs. Placebo)		0.668
95% CI for Hedges' g		-0.0821, 1.4173

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 3		
n	19	20
LS Mean (SE)	5.01 (2.363)	12.15 (2.325)
95% CI for the LS Mean	0.22, 9.80	7.44, 16.86
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.14 (3.323)
95% CI for the LS Mean		0.40, 13.87
p-value		0.0385
Hedges' g (Zuranolone vs. Placebo)		0.674
95% CI for Hedges' g		0.0286, 1.3195
Day 8		
n	20	20
LS Mean (SE)	11.28 (3.148)	18.53 (3.104)
95% CI for the LS Mean	4.88, 17.67	12.22, 24.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.25 (4.427)
95% CI for the LS Mean		-1.74, 16.24
p-value		0.1106
Hedges' g (Zuranolone vs. Placebo)		0.508
95% CI for Hedges' g		-0.1221, 1.1372

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	15.13 (4.241)	23.72 (4.159)
95% CI for the LS Mean	6.51, 23.74	15.27, 32.17
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.59 (5.944)
95% CI for the LS Mean		-3.48, 20.67
p-value		0.1573
Hedges' g (Zuranolone vs. Placebo)		0.448
95% CI for Hedges' g		-0.1794, 1.0757
Day 21		
n	20	21
LS Mean (SE)	18.03 (4.409)	26.97 (4.302)
95% CI for the LS Mean	9.08, 26.97	18.25, 35.70
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.95 (6.164)
95% CI for the LS Mean		-3.56, 21.45
p-value		0.1553
Hedges' g (Zuranolone vs. Placebo)		0.445
95% CI for Hedges' g		-0.1751, 1.0646

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 45		
n	20	20
LS Mean (SE)	21.83 (4.145)	32.19 (4.069)
95% CI for the LS Mean	13.39, 30.26	23.92, 40.47
Difference (Zuranolone - Placebo)		
LS Mean (SE)		10.37 (5.812)
95% CI for the LS Mean		-1.46, 22.20
p-value		0.0837
Hedges' g (Zuranolone vs. Placebo)		0.553
95% CI for Hedges' g		-0.0786, 1.1844

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 3		
n	33	39
LS Mean (SE)	2.91 (1.536)	6.70 (1.402)
95% CI for the LS Mean	-0.15, 5.98	3.90, 9.50
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.78 (2.097)
95% CI for the LS Mean		-0.41, 7.97
p-value		0.0761
Hedges' g (Zuranolone vs. Placebo)		0.422
95% CI for Hedges' g		-0.0468, 0.8905
Day 8		
n	34	42
LS Mean (SE)	11.25 (2.253)	12.26 (2.031)
95% CI for the LS Mean	6.75, 15.75	8.21, 16.31
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.01 (3.046)
95% CI for the LS Mean		-5.07, 7.09
p-value		0.7412
Hedges' g (Zuranolone vs. Placebo)		0.076
95% CI for Hedges' g		-0.3766, 0.5281

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	13.24 (2.708)	17.88 (2.443)
95% CI for the LS Mean	7.84, 18.63	13.01, 22.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.64 (3.658)
95% CI for the LS Mean		-2.65, 11.94
p-value		0.2083
Hedges' g (Zuranolone vs. Placebo)		0.294
95% CI for Hedges' g		-0.1669, 0.7547
Day 21		
n	34	41
LS Mean (SE)	15.34 (2.616)	16.18 (2.373)
95% CI for the LS Mean	10.12, 20.56	11.45, 20.91
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.84 (3.543)
95% CI for the LS Mean		-6.23, 7.91
p-value		0.8130
Hedges' g (Zuranolone vs. Placebo)		0.055
95% CI for Hedges' g		-0.4002, 0.5092

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 45		
n	31	41
LS Mean (SE)	19.65 (2.865)	24.36 (2.542)
95% CI for the LS Mean	13.93, 25.37	19.28, 29.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.71 (3.841)
95% CI for the LS Mean		-2.96, 12.38
p-value		0.2244
Hedges' g (Zuranolone vs. Placebo)		0.289
95% CI for Hedges' g		-0.1800, 0.7577

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
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3.1.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 3		
n	31	32
LS Mean (SE)	6.24 (1.871)	7.79 (1.841)
95% CI for the LS Mean	2.49, 9.98	4.11, 11.48
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.56 (2.627)
95% CI for the LS Mean		-3.70, 6.82
p-value		0.5560
Hedges' g (Zuranolone vs. Placebo)		0.147
95% CI for Hedges' g		-0.3472, 0.6420
Day 8		
n	31	32
LS Mean (SE)	12.07 (2.502)	11.85 (2.462)
95% CI for the LS Mean	7.07, 17.08	6.93, 16.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.22 (3.512)
95% CI for the LS Mean		-7.24, 6.80
p-value		0.9502
Hedges' g (Zuranolone vs. Placebo)		-0.016
95% CI for Hedges' g		-0.5095, 0.4783

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	11.20 (3.044)	17.26 (2.996)
95% CI for the LS Mean	5.12, 17.29	11.27, 23.25
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.06 (4.272)
95% CI for the LS Mean		-2.49, 14.60
p-value		0.1613
Hedges' g (Zuranolone vs. Placebo)		0.353
95% CI for Hedges' g		-0.1449, 0.8507
Day 21		
n	30	31
LS Mean (SE)	17.03 (3.176)	18.67 (3.126)
95% CI for the LS Mean	10.68, 23.39	12.42, 24.92
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.64 (4.457)
95% CI for the LS Mean		-7.28, 10.55
p-value		0.7147
Hedges' g (Zuranolone vs. Placebo)		0.093
95% CI for Hedges' g		-0.4094, 0.5951

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 45		
n	29	30
LS Mean (SE)	19.88 (3.053)	25.48 (3.004)
95% CI for the LS Mean	13.77, 26.00	19.47, 31.50
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.60 (4.284)
95% CI for the LS Mean		-2.98, 14.18
p-value		0.1963
Hedges' g (Zuranolone vs. Placebo)		0.336
95% CI for Hedges' g		-0.1781, 0.8499

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 3		
n	41	40
LS Mean (SE)	3.55 (1.645)	6.43 (1.654)
95% CI for the LS Mean	0.27, 6.82	3.14, 9.73
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.89 (2.364)
95% CI for the LS Mean		-1.82, 7.59
p-value		0.2261
Hedges' g (Zuranolone vs. Placebo)		0.269
95% CI for Hedges' g		-0.1689, 0.7061
Day 8		
n	43	43
LS Mean (SE)	11.77 (2.021)	14.21 (2.017)
95% CI for the LS Mean	7.75, 15.80	10.19, 18.23
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.44 (2.882)
95% CI for the LS Mean		-3.30, 8.17
p-value		0.4007
Hedges' g (Zuranolone vs. Placebo)		0.181
95% CI for Hedges' g		-0.2429, 0.6042

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	16.23 (2.645)	20.33 (2.633)
95% CI for the LS Mean	10.96, 21.50	15.09, 25.57
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.10 (3.753)
95% CI for the LS Mean		-3.38, 11.57
p-value		0.2784
Hedges' g (Zuranolone vs. Placebo)		0.236
95% CI for Hedges' g		-0.1932, 0.6652
Day 21		
n	43	43
LS Mean (SE)	15.59 (2.569)	20.93 (2.560)
95% CI for the LS Mean	10.47, 20.70	15.83, 26.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.34 (3.648)
95% CI for the LS Mean		-1.92, 12.60
p-value		0.1473
Hedges' g (Zuranolone vs. Placebo)		0.313
95% CI for Hedges' g		-0.1125, 0.7381

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 45		
n	40	43
LS Mean (SE)	19.85 (2.906)	28.56 (2.863)
95% CI for the LS Mean	14.07, 25.64	22.85, 34.26
Difference (Zuranolone - Placebo)		
LS Mean (SE)		8.70 (4.098)
95% CI for the LS Mean		0.54, 16.86
p-value		0.0370
Hedges' g (Zuranolone vs. Placebo)		0.462
95% CI for Hedges' g		0.0258, 0.8983

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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3.1.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 3		
n	10	10
LS Mean (SE)	4.09 (1.902)	8.94 (1.904)
95% CI for the LS Mean	0.06, 8.11	4.91, 12.97
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.85 (2.817)
95% CI for the LS Mean		-1.10, 10.81
p-value		0.1036
Hedges' g (Zuranolone vs. Placebo)		0.738
95% CI for Hedges' g		-0.1681, 1.6436
Day 8		
n	10	10
LS Mean (SE)	13.79 (4.960)	11.44 (4.961)
95% CI for the LS Mean	3.30, 24.27	0.95, 21.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.35 (7.064)
95% CI for the LS Mean		-17.27, 12.57
p-value		0.7438
Hedges' g (Zuranolone vs. Placebo)		-0.142
95% CI for Hedges' g		-1.0199, 0.7353

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	18.19 (6.117)	16.94 (6.118)
95% CI for the LS Mean	5.29, 31.08	4.04, 29.84
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.25 (8.692)
95% CI for the LS Mean		-19.55, 17.06
p-value		0.8876
Hedges' g (Zuranolone vs. Placebo)		-0.061
95% CI for Hedges' g		-0.9382, 0.8153
Day 21		
n	10	10
LS Mean (SE)	16.79 (5.340)	17.74 (5.341)
95% CI for the LS Mean	5.52, 28.06	6.47, 29.01
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.95 (7.599)
95% CI for the LS Mean		-15.07, 16.97
p-value		0.9017
Hedges' g (Zuranolone vs. Placebo)		0.054
95% CI for Hedges' g		-0.8230, 0.9304

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 45		
n	9	10
LS Mean (SE)	23.77 (5.198)	20.44 (5.131)
95% CI for the LS Mean	12.56, 34.98	9.34, 31.54
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.33 (7.357)
95% CI for the LS Mean		-19.19, 12.53
p-value		0.6583
Hedges' g (Zuranolone vs. Placebo)		-0.199
95% CI for Hedges' g		-1.1013, 0.7042

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 3		
n	62	62
LS Mean (SE)	4.67 (1.383)	7.04 (1.375)
95% CI for the LS Mean	1.93, 7.41	4.32, 9.77
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.38 (1.963)
95% CI for the LS Mean		-1.51, 6.26
p-value		0.2283
Hedges' g (Zuranolone vs. Placebo)		0.216
95% CI for Hedges' g		-0.1369, 0.5692
Day 8		
n	64	65
LS Mean (SE)	11.48 (1.670)	13.60 (1.653)
95% CI for the LS Mean	8.17, 14.78	10.33, 16.87
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.12 (2.360)
95% CI for the LS Mean		-2.55, 6.79
p-value		0.3701
Hedges' g (Zuranolone vs. Placebo)		0.157
95% CI for Hedges' g		-0.1882, 0.5032

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	13.29 (2.109)	19.45 (2.085)
95% CI for the LS Mean	9.11, 17.46	15.32, 23.58
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.17 (2.974)
95% CI for the LS Mean		0.28, 12.05
p-value		0.0402
Hedges' g (Zuranolone vs. Placebo)		0.366
95% CI for Hedges' g		0.0150, 0.7165
Day 21		
n	63	64
LS Mean (SE)	15.94 (2.179)	20.39 (2.155)
95% CI for the LS Mean	11.62, 20.25	16.12, 24.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.45 (3.073)
95% CI for the LS Mean		-1.63, 10.54
p-value		0.1497
Hedges' g (Zuranolone vs. Placebo)		0.256
95% CI for Hedges' g		-0.0935, 0.6050

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 45		
n	60	63
LS Mean (SE)	19.20 (2.315)	28.41 (2.277)
95% CI for the LS Mean	14.61, 23.78	23.90, 32.92
Difference (Zuranolone - Placebo)		
LS Mean (SE)		9.22 (3.254)
95% CI for the LS Mean		2.77, 15.66
p-value		0.0054
Hedges' g (Zuranolone vs. Placebo)		0.508
95% CI for Hedges' g		0.1485, 0.8669

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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3.1.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 3		
n	58	62
LS Mean (SE)	5.77 (1.375)	7.16 (1.320)
95% CI for the LS Mean	3.04, 8.49	4.54, 9.77
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.39 (1.915)
95% CI for the LS Mean		-2.40, 5.18
p-value		0.4698
Hedges' g (Zuranolone vs. Placebo)		0.132
95% CI for Hedges' g		-0.2268, 0.4901
Day 8		
n	59	65
LS Mean (SE)	13.28 (1.727)	12.86 (1.639)
95% CI for the LS Mean	9.86, 16.70	9.62, 16.11
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.42 (2.388)
95% CI for the LS Mean		-5.15, 4.31
p-value		0.8611
Hedges' g (Zuranolone vs. Placebo)		-0.031
95% CI for Hedges' g		-0.3838, 0.3211

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	15.21 (2.269)	19.22 (2.156)
95% CI for the LS Mean	10.72, 19.71	14.95, 23.49
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.00 (3.135)
95% CI for the LS Mean		-2.20, 10.21
p-value		0.2042
Hedges' g (Zuranolone vs. Placebo)		0.229
95% CI for Hedges' g		-0.1259, 0.5839
Day 21		
n	58	65
LS Mean (SE)	17.00 (2.290)	19.73 (2.169)
95% CI for the LS Mean	12.46, 21.53	15.43, 24.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.73 (3.160)
95% CI for the LS Mean		-3.53, 8.99
p-value		0.3891
Hedges' g (Zuranolone vs. Placebo)		0.155
95% CI for Hedges' g		-0.1994, 0.5097

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 45		
n	55	64
LS Mean (SE)	20.70 (2.466)	27.86 (2.317)
95% CI for the LS Mean	15.81, 25.58	23.27, 32.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.16 (3.389)
95% CI for the LS Mean		0.45, 13.88
p-value		0.0367
Hedges' g (Zuranolone vs. Placebo)		0.386
95% CI for Hedges' g		0.0225, 0.7499

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 3		
n	14	10
LS Mean (SE)	0.83 (2.760)	6.63 (3.333)
95% CI for the LS Mean	-4.89, 6.55	-0.29, 13.55
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.80 (4.407)
95% CI for the LS Mean		-3.34, 14.94
p-value		0.2016
Hedges' g (Zuranolone vs. Placebo)		0.526
95% CI for Hedges' g		-0.2990, 1.3511
Day 8		
n	15	10
LS Mean (SE)	7.01 (3.626)	14.93 (4.438)
95% CI for the LS Mean	-0.51, 14.54	5.72, 24.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.92 (5.798)
95% CI for the LS Mean		-4.10, 19.94
p-value		0.1859
Hedges' g (Zuranolone vs. Placebo)		0.539
95% CI for Hedges' g		-0.2750, 1.3530

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	10.10 (3.799)	17.23 (4.601)
95% CI for the LS Mean	2.19, 18.02	7.63, 26.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.12 (6.032)
95% CI for the LS Mean		-5.44, 19.68
p-value		0.2510
Hedges' g (Zuranolone vs. Placebo)		0.472
95% CI for Hedges' g		-0.3502, 1.2946
Day 21		
n	15	9
LS Mean (SE)	13.35 (3.582)	20.99 (4.497)
95% CI for the LS Mean	5.91, 20.78	11.69, 30.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.64 (5.823)
95% CI for the LS Mean		-4.39, 19.68
p-value		0.2021
Hedges' g (Zuranolone vs. Placebo)		0.534
95% CI for Hedges' g		-0.3057, 1.3746

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-mmrm-201-by.sas:t-bimf-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by History of PPD: 217-PPD-201B - ITT population

Page: 6 of 6

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 45		
n	14	9
LS Mean (SE)	16.96 (2.920)	22.48 (3.625)
95% CI for the LS Mean	10.87, 23.05	14.93, 30.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.52 (4.753)
95% CI for the LS Mean		-4.36, 15.40
p-value		0.2585
Hedges' g (Zuranolone vs. Placebo)		0.478
95% CI for Hedges' g		-0.3705, 1.3269

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

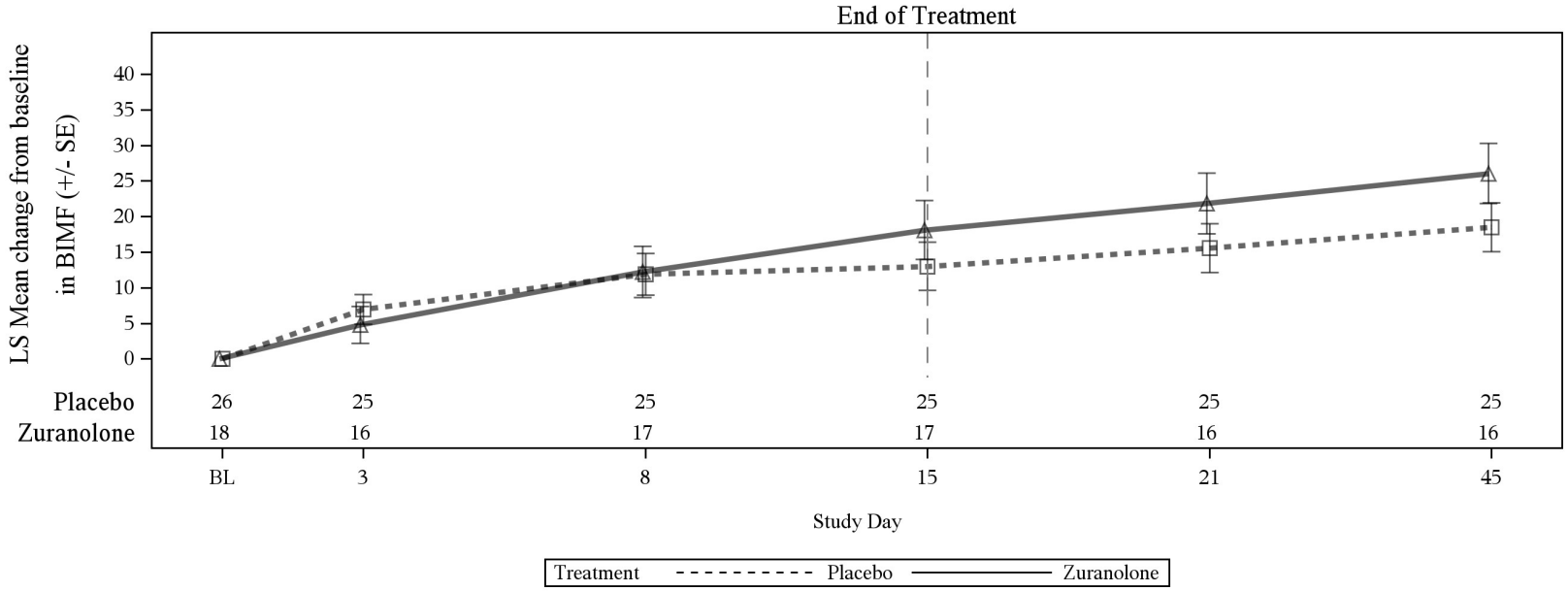
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3.1.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

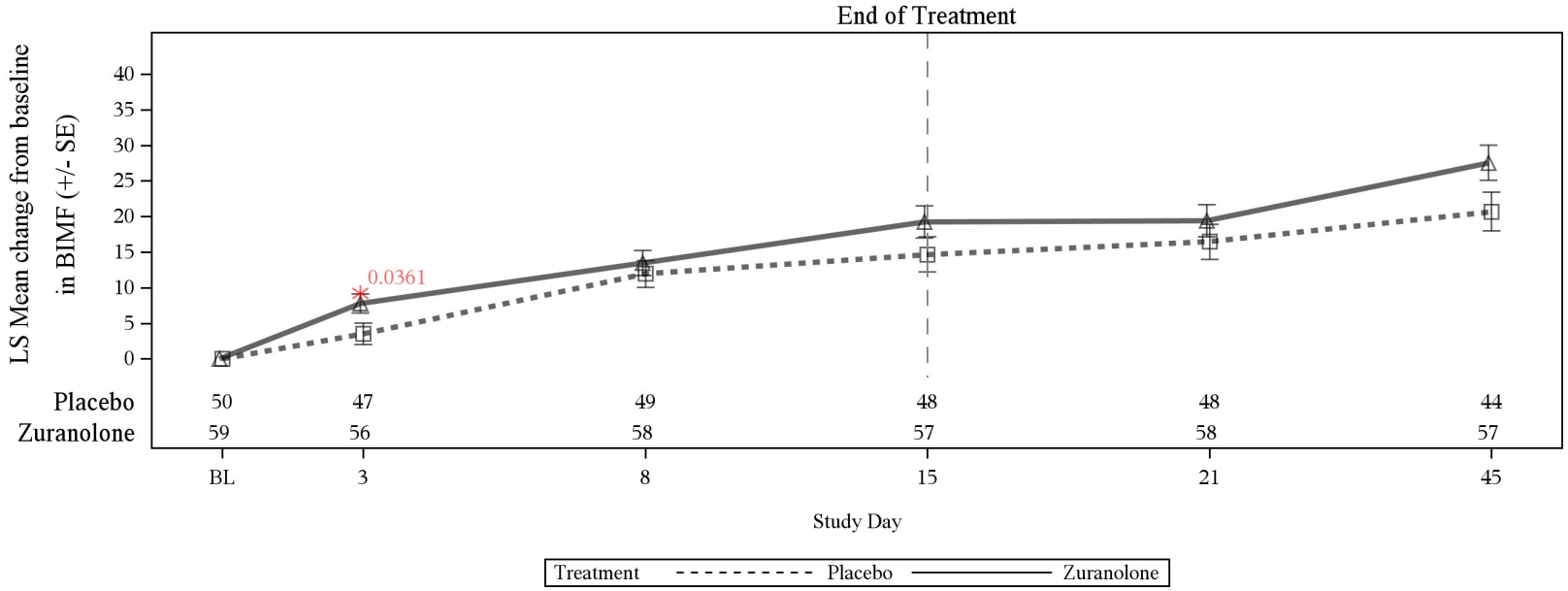
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

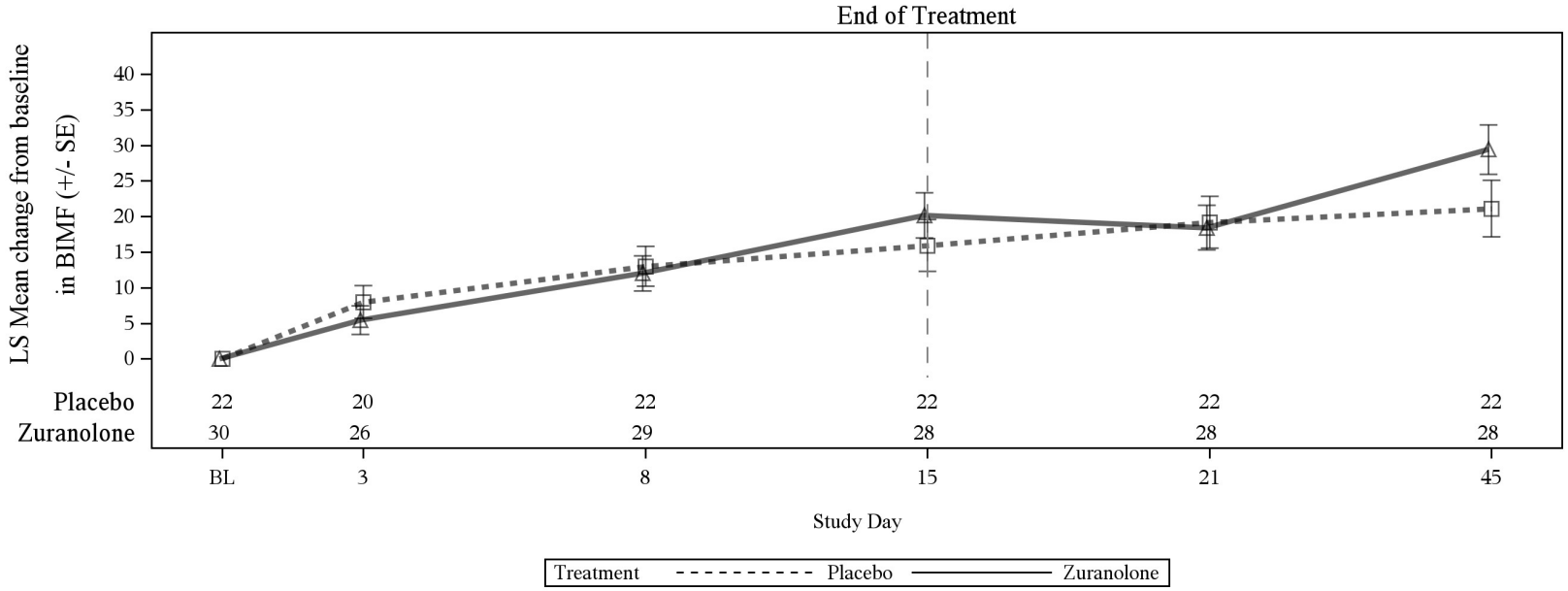
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

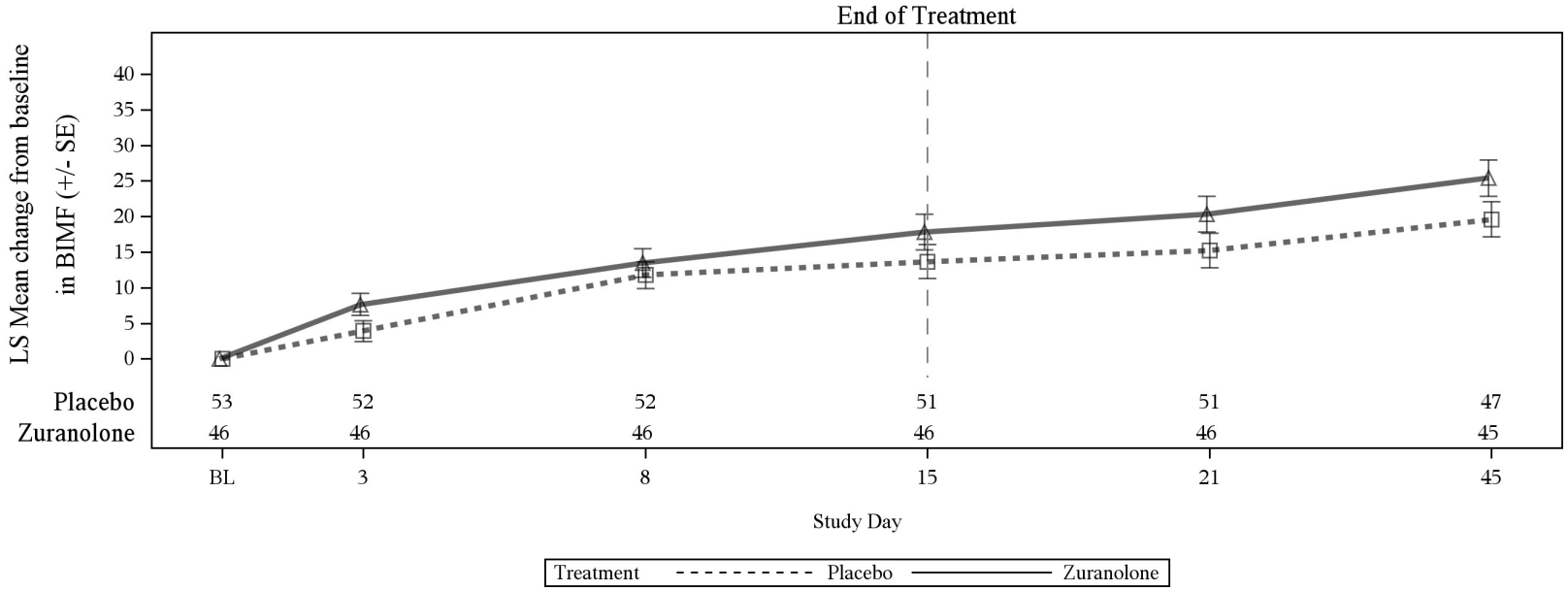
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

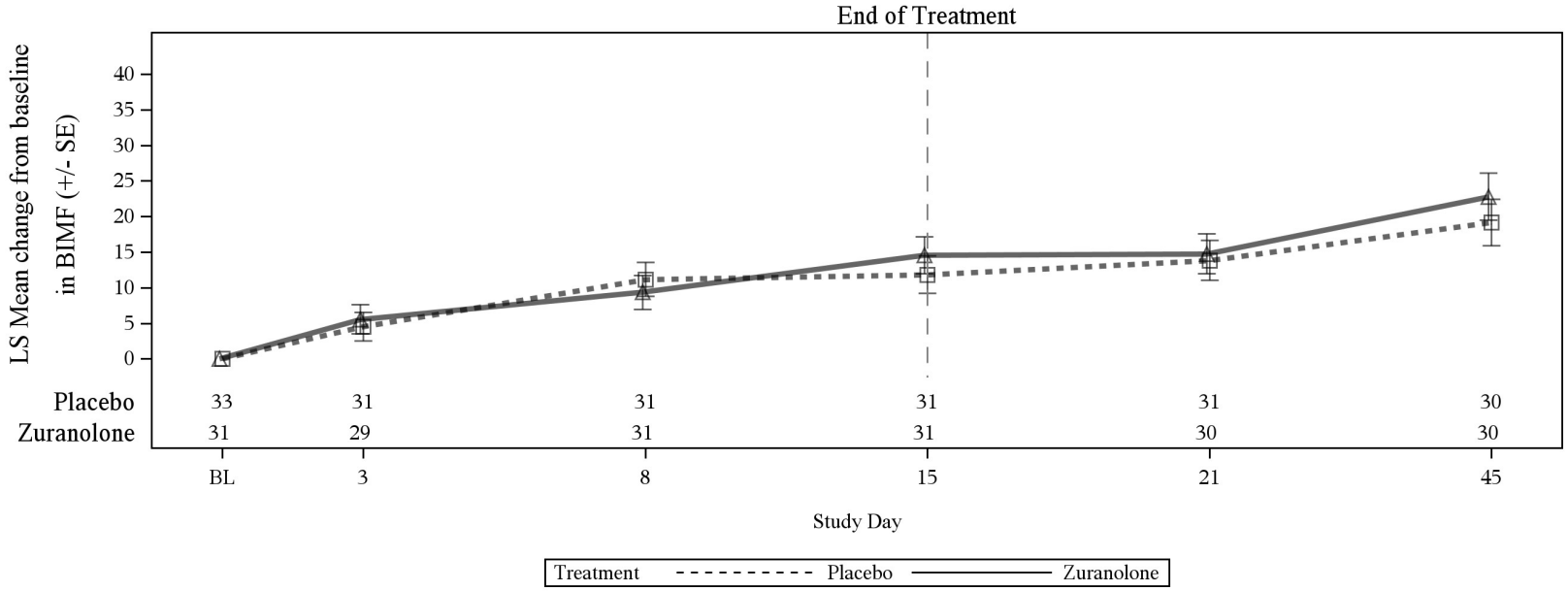
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

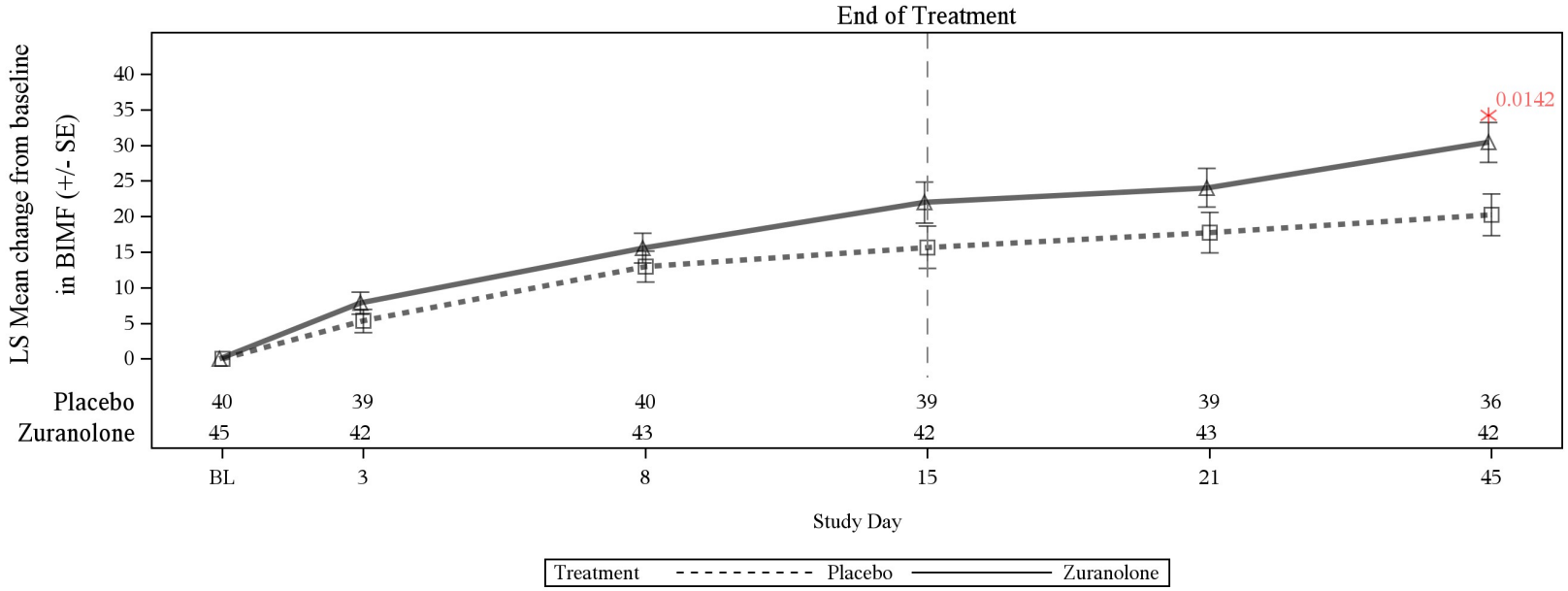
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

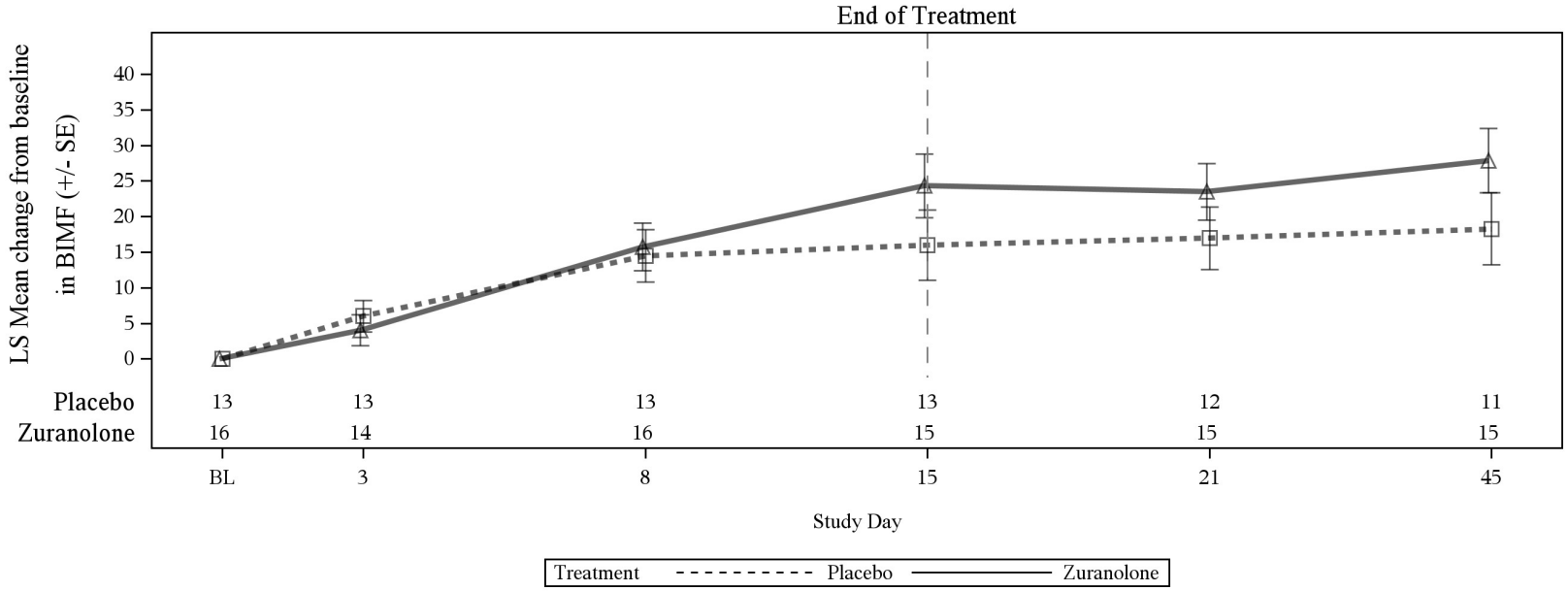
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

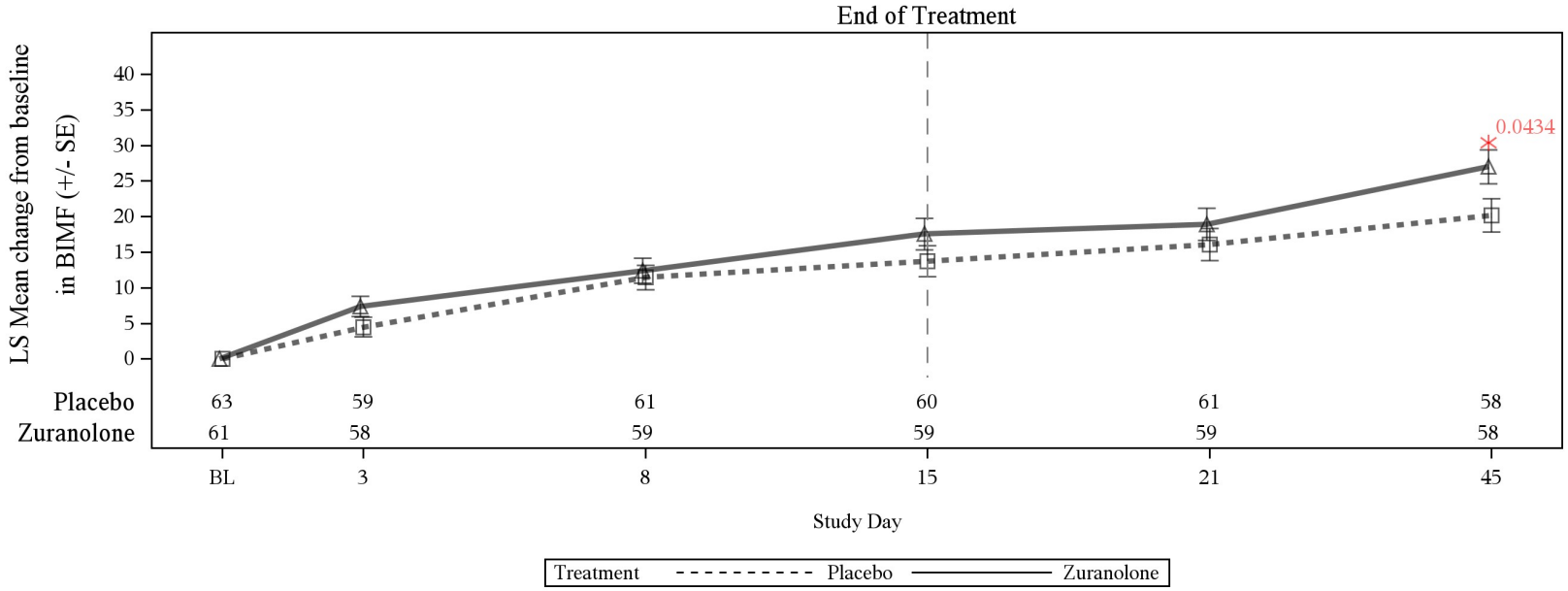
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

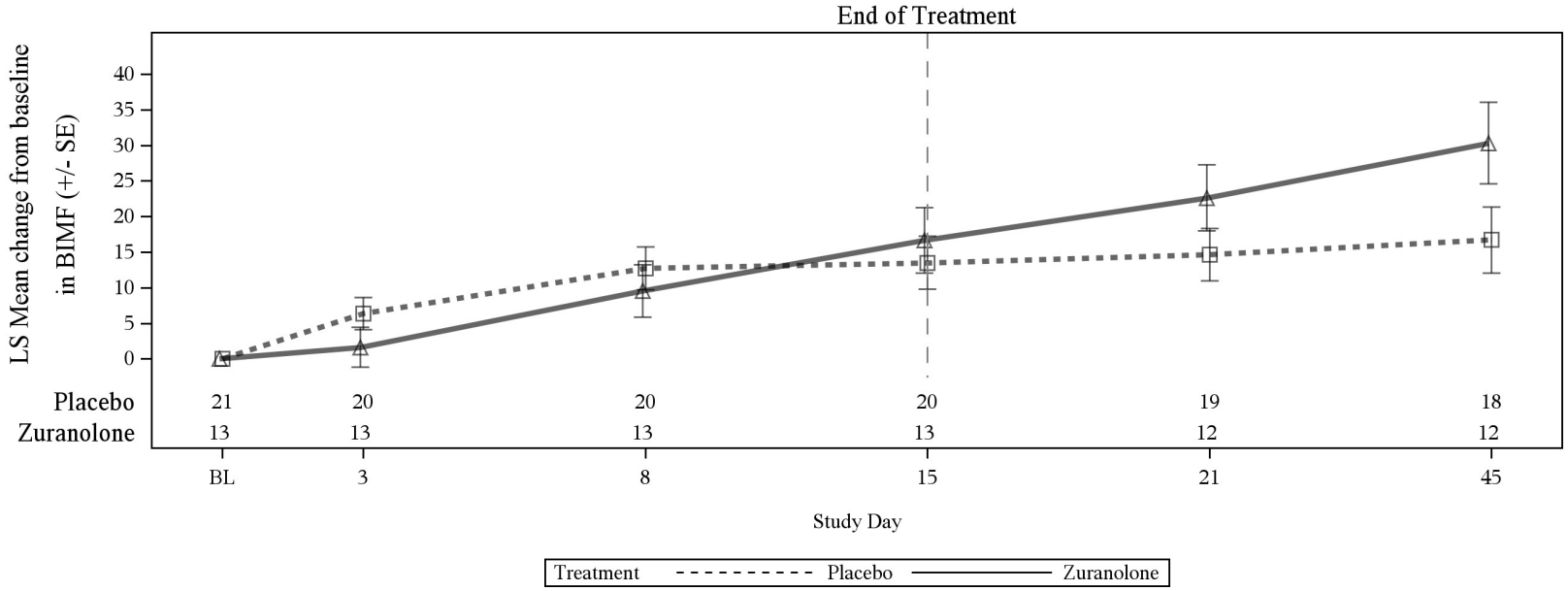
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

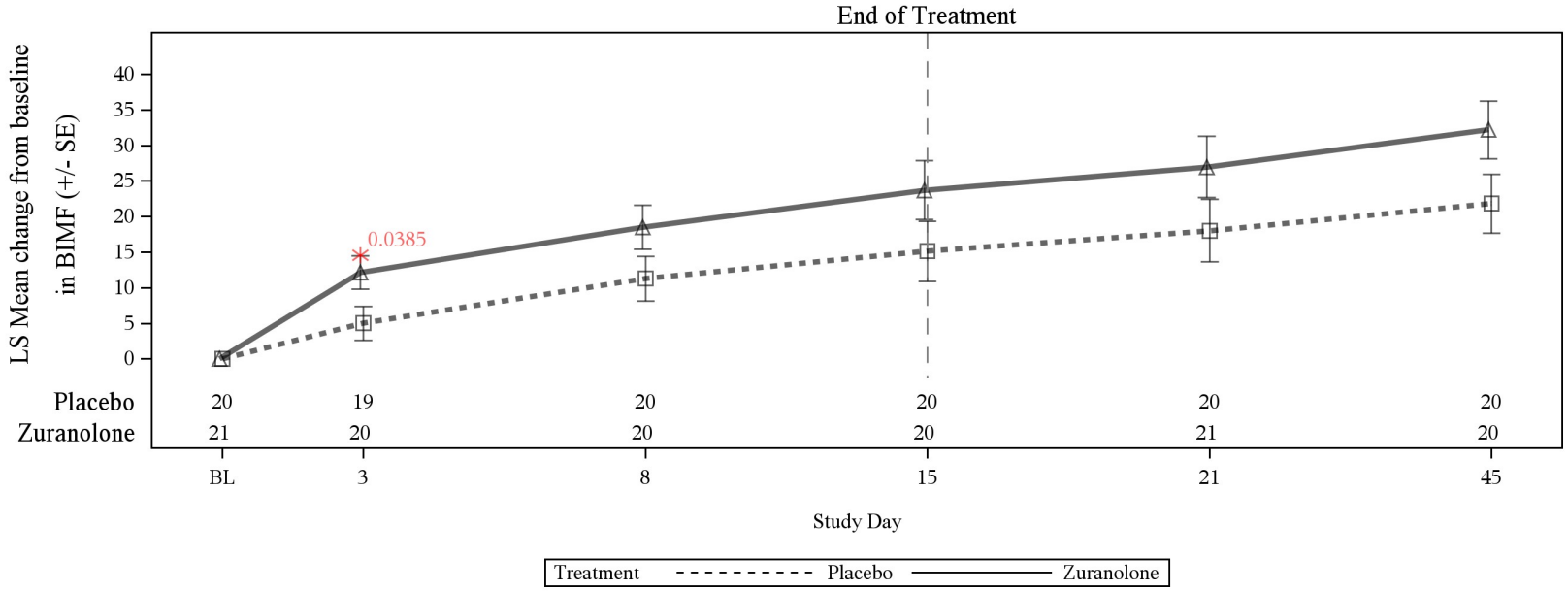
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

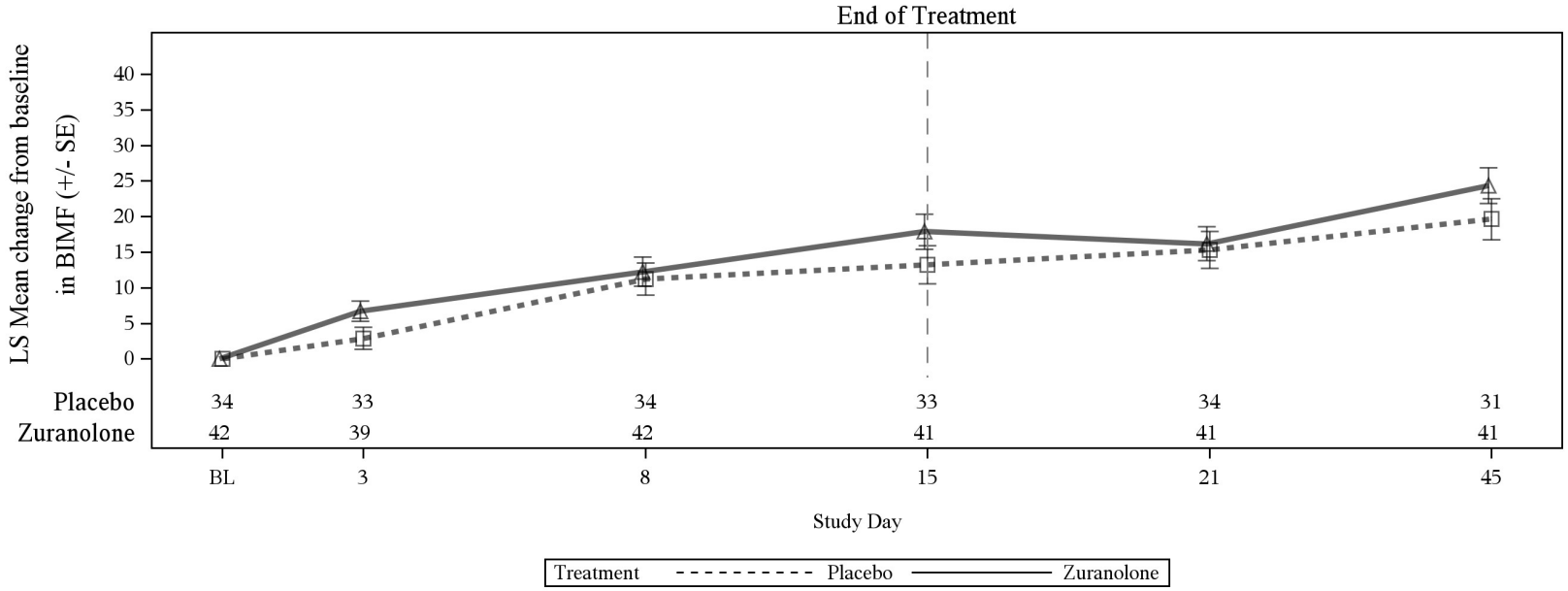
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

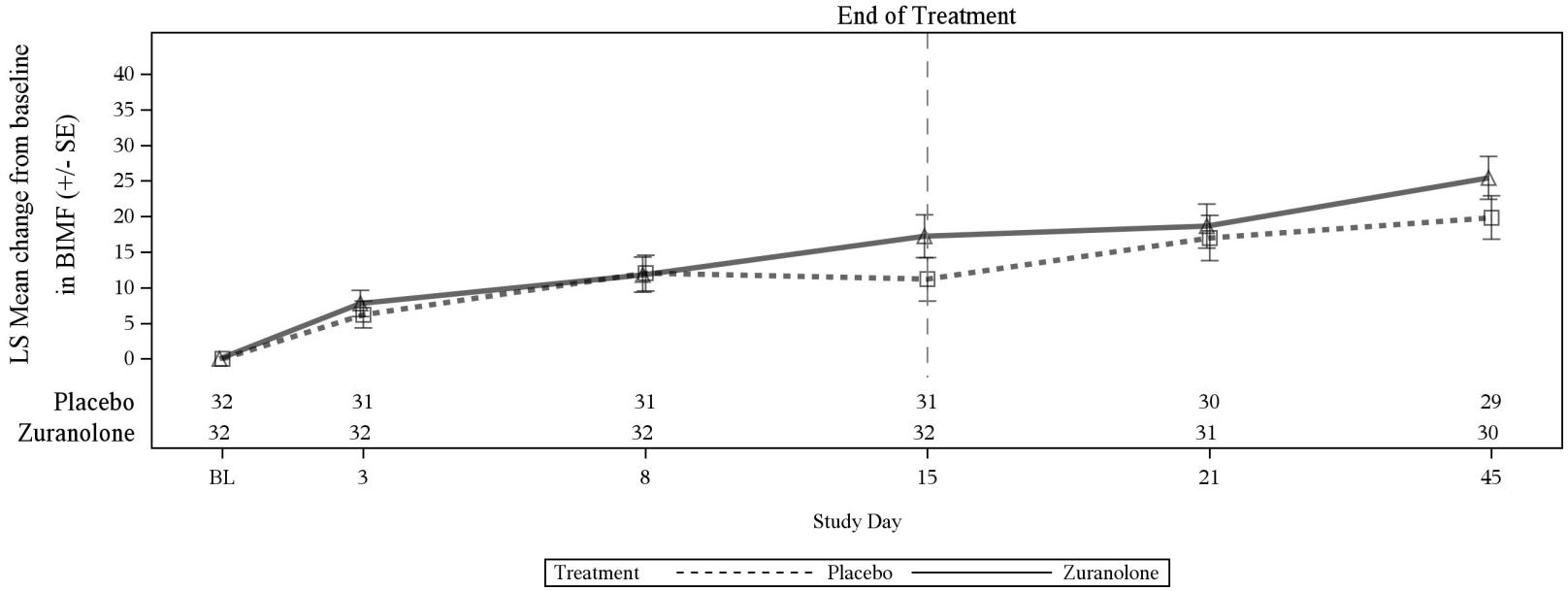
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

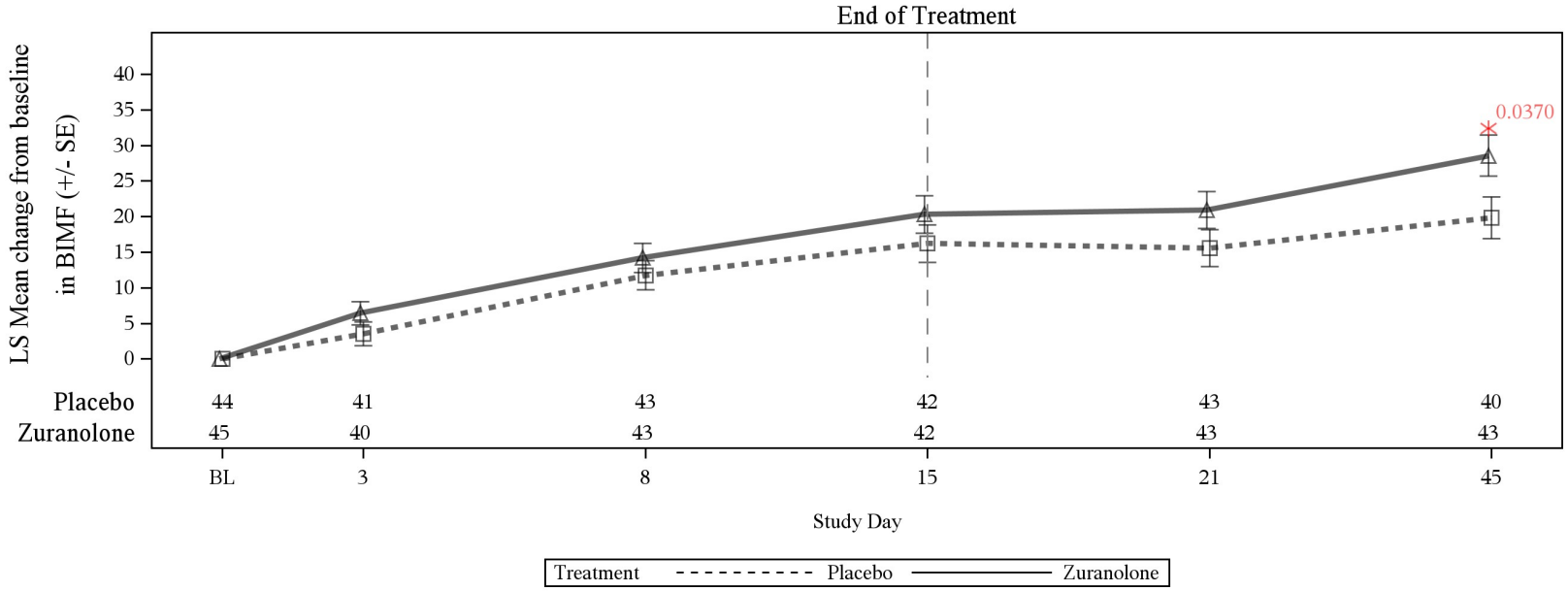
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

Page: 13 of 17

Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

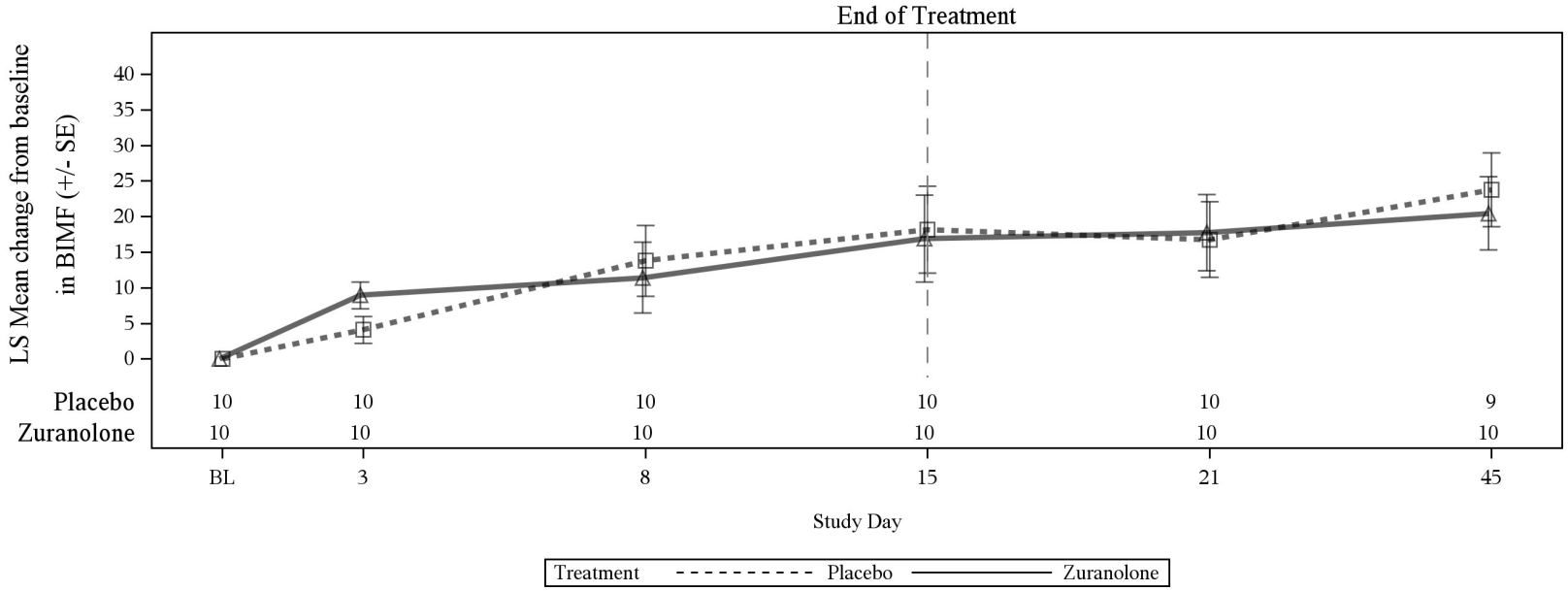
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

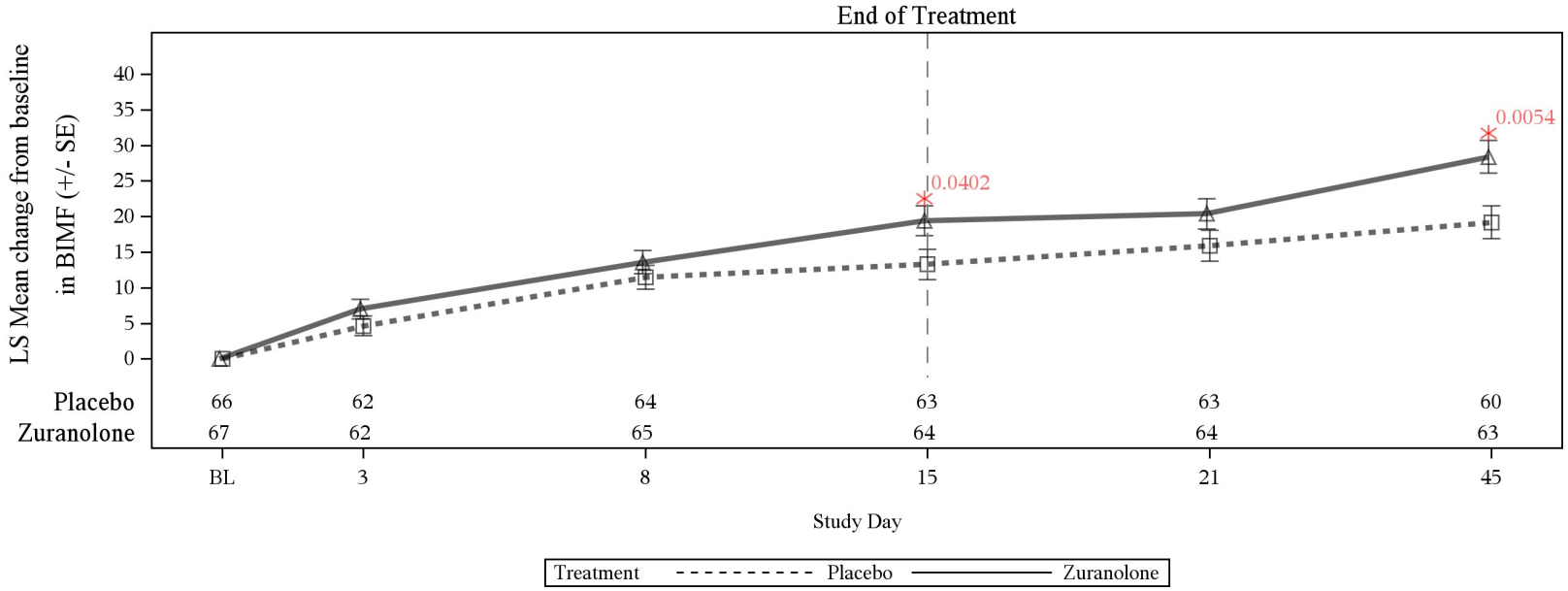
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

Page: 15 of 17

Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

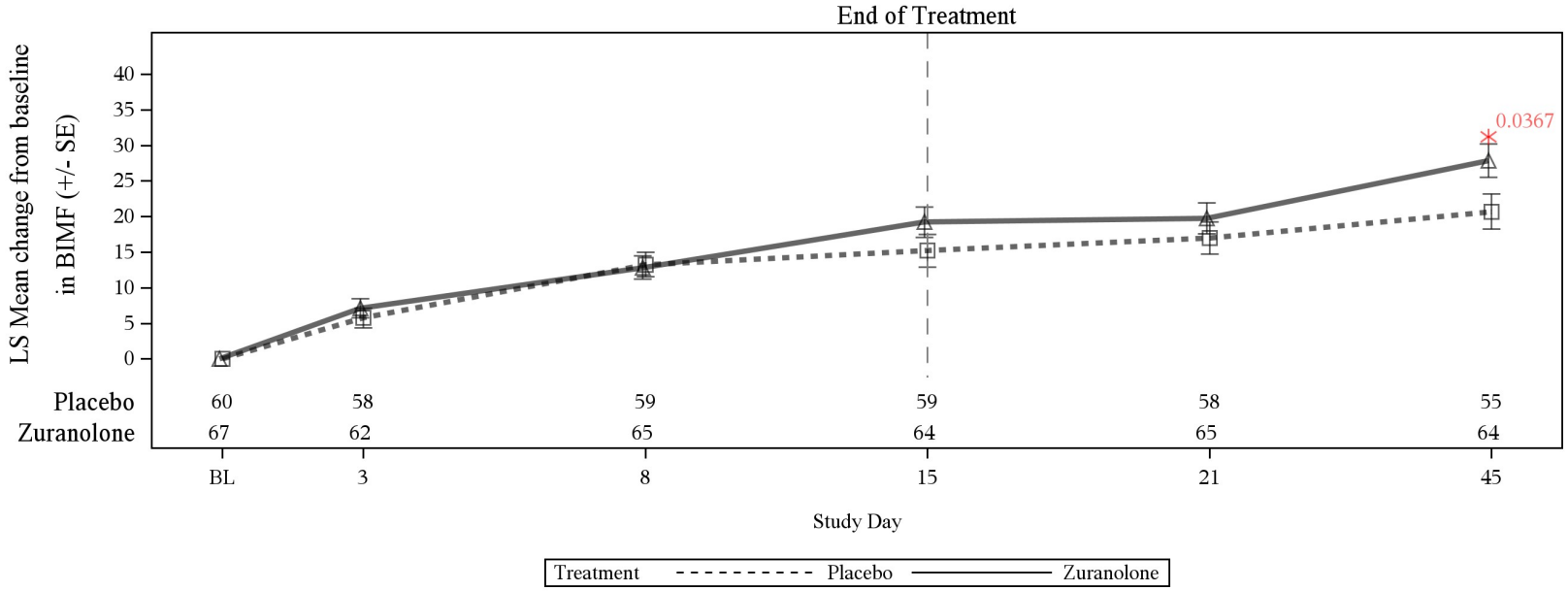
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

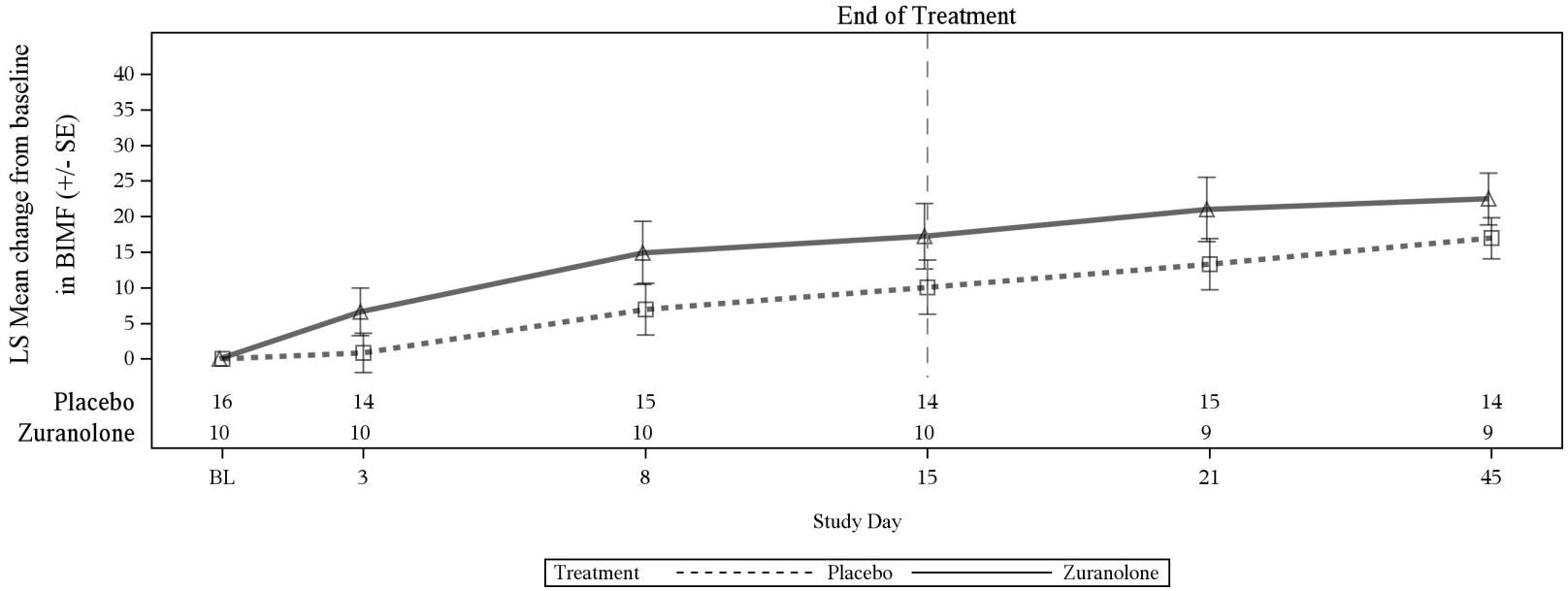
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Total Score by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-mmrm-201-by.sas:f-bimf-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

3.1.2 Ansprechen

3.1.2.1 Responder-Analysen

3.1.2.1 .1 ITT-Population

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with a response, n (%) [2]	7 (9.3)	11 (14.5)
Number of subjects with missing evaluation, n (%)	3 (4.0)	4 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.451
95% CI for the RR		(0.600, 3.508)
p-value for RR		0.4081
OR - Odds Ratio (Zuranolone vs. Placebo)		1.355
95% CI for the OR		(0.496, 3.700)
p-value for OR		0.5529
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.
[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-ovr.sas:t-bimf-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 2 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with a response, n (%) [2]	19 (25.3)	23 (30.3)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.118
95% CI for the RR		(0.679, 1.840)
p-value for RR		0.6609
OR - Odds Ratio (Zuranolone vs. Placebo)		1.074
95% CI for the OR		(0.526, 2.194)
p-value for OR		0.8440
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-ovr.sas:t-bimf-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with a response, n (%) [2]	20 (26.7)	35 (46.1)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.616
95% CI for the RR		(1.040, 2.513)
p-value for RR		0.0330
OR - Odds Ratio (Zuranolone vs. Placebo)		2.020
95% CI for the OR		(1.001, 4.077)
p-value for OR		0.0496
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-ovr.sas:t-bimf-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with a response, n (%) [2]	35 (46.7)	35 (46.1)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.924
95% CI for the RR		(0.661, 1.290)
p-value for RR		0.6410
OR - Odds Ratio (Zuranolone vs. Placebo)		0.822
95% CI for the OR		(0.419, 1.613)
p-value for OR		0.5684
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-ovr.sas:t-bimf-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	37 (49.3)	49 (64.5)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.223
95% CI for the RR		(0.914, 1.636)
p-value for RR		0.1753
OR - Odds Ratio (Zuranolone vs. Placebo)		1.687
95% CI for the OR		(0.843, 3.374)
p-value for OR		0.1393
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-ovr.sas:t-bimf-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.1.2.1 .2 Subgruppen

3.1.2.1 .2 .1 Interaktionstest

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	20 (26.7)	35 (46.1)	
Number of subjects with response at Day 45, n (%)	37 (49.3)	49 (64.5)	
Age Group (years)			0.5672
Day 15			
18 - 24, n / N (%)	6/25 (24.0)	7/17 (41.2)	
25 - 45, n / N (%)	14/50 (28.0)	28/59 (47.5)	
Day 45			
18 - 24, n / N (%)	13/25 (52.0)	10/17 (58.8)	
25 - 45, n / N (%)	24/50 (48.0)	39/59 (66.1)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-int.sas:t-bimf-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.0460
Day 15			
<28, n / N (%)	6/22 (27.3)	14/30 (46.7)	
>=28, n / N (%)	14/53 (26.4)	21/46 (45.7)	
Day 45			
<28, n / N (%)	14/22 (63.6)	20/30 (66.7)	
>=28, n / N (%)	23/53 (43.4)	29/46 (63.0)	
Race Group (Black or African American, White)			0.2594
Day 15			
Black or African American, n / N (%)	7/32 (21.9)	11/31 (35.5)	
White, n / N (%)	11/40 (27.5)	24/44 (54.5)	
Day 45			
Black or African American, n / N (%)	18/32 (56.3)	20/31 (64.5)	
White, n / N (%)	17/40 (42.5)	29/44 (65.9)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-int.sas:t-bimf-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.3130
Day 15			
Yes, n / N (%)	4/13 (30.8)	10/16 (62.5)	
No, n / N (%)	16/62 (25.8)	25/60 (41.7)	
Day 45			
Yes, n / N (%)	5/13 (38.5)	10/16 (62.5)	
No, n / N (%)	32/62 (51.6)	39/60 (65.0)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-int.sas:t-bimf-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.7804(a) 0.8584(b) 0.8736(c)
Day 15			
<=24.9, n / N (%)	5/21 (23.8)	6/13 (46.2)	
25-29.9, n / N (%)	6/20 (30.0)	9/21 (42.9)	
>=30, n / N (%)	9/34 (26.5)	20/42 (47.6)	
Day 45			
<=24.9, n / N (%)	6/21 (28.6)	7/13 (53.8)	
25-29.9, n / N (%)	12/20 (60.0)	12/21 (57.1)	
>=30, n / N (%)	19/34 (55.9)	30/42 (71.4)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.1820
Day 15			
3rd Trimester, n / N (%)	7/32 (21.9)	12/32 (37.5)	
Postpartum, n / N (%)	13/43 (30.2)	23/44 (52.3)	
Day 45			
3rd Trimester, n / N (%)	19/32 (59.4)	19/32 (59.4)	
Postpartum, n / N (%)	18/43 (41.9)	30/44 (68.2)	
Family History of PPD			0.2852
Day 15			
Yes, n / N (%)	4/10 (40.0)	4/10 (40.0)	
No/Unknown, n / N (%)	16/65 (24.6)	31/66 (47.0)	
Day 45			
Yes, n / N (%)	6/10 (60.0)	6/10 (60.0)	
No/Unknown, n / N (%)	31/65 (47.7)	43/66 (65.2)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.3302
Day 15			
1st Episode, n / N (%)	17/59 (28.8)	31/66 (47.0)	
Recurrent Episode, n / N (%)	3/16 (18.8)	4/10 (40.0)	
Day 45			
1st Episode, n / N (%)	30/59 (50.8)	42/66 (63.6)	
Recurrent Episode, n / N (%)	7/16 (43.8)	7/10 (70.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	4/8 (50.0)	4/10 (40.0)	
>=20, n / N (%)	16/67 (23.9)	31/66 (47.0)	
Day 45			
<20, n / N (%)	5/8 (62.5)	8/10 (80.0)	
>=20, n / N (%)	32/67 (47.8)	41/66 (62.1)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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3.1.2.1 .2 .2 Subgruppenanalysen

3.1.2.1 .2 .2 .1 Alter

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 1 of 6

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 3		
Number of subjects with a response, n (%) [2]	3 (12.0)	2 (11.8)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.842
95% CI for the RR		(0.165, 4.301)
p-value for RR		0.8367
Day 8		
Number of subjects with a response, n (%) [2]	7 (28.0)	6 (35.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.083
95% CI for the RR		(0.487, 2.409)
p-value for RR		0.8448

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 15		
Number of subjects with a response, n (%) [2]	6 (24.0)	7 (41.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.474
95% CI for the RR		(0.628, 3.460)
p-value for RR		0.3724
Day 21		
Number of subjects with a response, n (%) [2]	11 (44.0)	9 (52.9)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.034
95% CI for the RR		(0.540, 1.980)
p-value for RR		0.9199

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 45		
Number of subjects with a response, n (%) [2]	13 (52.0)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.972
95% CI for the RR		(0.537, 1.761)
p-value for RR		0.9255

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 3		
Number of subjects with a response, n (%) [2]	4 (8.0)	9 (15.3)
Number of subjects with missing evaluation, n (%)	3 (6.0)	3 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.848
95% CI for the RR		(0.609, 5.608)
p-value for RR		0.2782
Day 8		
Number of subjects with a response, n (%) [2]	12 (24.0)	17 (28.8)
Number of subjects with missing evaluation, n (%)	1 (2.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.164
95% CI for the RR		(0.626, 2.161)
p-value for RR		0.6315

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 15		
Number of subjects with a response, n (%) [2]	14 (28.0)	28 (47.5)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.643
95% CI for the RR		(0.988, 2.731)
p-value for RR		0.0556
Day 21		
Number of subjects with a response, n (%) [2]	24 (48.0)	26 (44.1)
Number of subjects with missing evaluation, n (%)	2 (4.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.890
95% CI for the RR		(0.601, 1.317)
p-value for RR		0.5598

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 45		
Number of subjects with a response, n (%) [2]	24 (48.0)	39 (66.1)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.335
95% CI for the RR		(0.942, 1.891)
p-value for RR		0.1043

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

3.1.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 3		
Number of subjects with a response, n (%) [2]	2 (9.1)	4 (13.3)
Number of subjects with missing evaluation, n (%)	2 (9.1)	4 (13.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.069
95% CI for the RR		(0.215, 5.309)
p-value for RR		0.9347
Day 8		
Number of subjects with a response, n (%) [2]	5 (22.7)	11 (36.7)
Number of subjects with missing evaluation, n (%)	0	1 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.176
95% CI for the RR		(0.486, 2.845)
p-value for RR		0.7187

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 15		
Number of subjects with a response, n (%) [2]	6 (27.3)	14 (46.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.247
95% CI for the RR		(0.549, 2.834)
p-value for RR		0.5974
Day 21		
Number of subjects with a response, n (%) [2]	14 (63.6)	12 (40.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.458
95% CI for the RR		(0.263, 0.798)
p-value for RR		0.0058

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 45		
Number of subjects with a response, n (%) [2]	14 (63.6)	20 (66.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.764
95% CI for the RR		(0.476, 1.225)
p-value for RR		0.2635

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 3		
Number of subjects with a response, n (%) [2]	5 (9.4)	7 (15.2)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.623
95% CI for the RR		(0.561, 4.697)
p-value for RR		0.3715
Day 8		
Number of subjects with a response, n (%) [2]	14 (26.4)	12 (26.1)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.994
95% CI for the RR		(0.522, 1.891)
p-value for RR		0.9851

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 15		
Number of subjects with a response, n (%) [2]	14 (26.4)	21 (45.7)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.739
95% CI for the RR		(1.020, 2.966)
p-value for RR		0.0421
Day 21		
Number of subjects with a response, n (%) [2]	21 (39.6)	23 (50.0)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.270
95% CI for the RR		(0.828, 1.948)
p-value for RR		0.2737

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 45		
Number of subjects with a response, n (%) [2]	23 (43.4)	29 (63.0)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.462
95% CI for the RR		(1.001, 2.136)
p-value for RR		0.0495

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

3.1.2.1 .2 .2 .3 Abstammung

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 3		
Number of subjects with a response, n (%) [2]	4 (12.5)	2 (6.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	2 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.514
95% CI for the RR		(0.103, 2.568)
p-value for RR		0.4175
Day 8		
Number of subjects with a response, n (%) [2]	8 (25.0)	6 (19.4)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.771
95% CI for the RR		(0.309, 1.922)
p-value for RR		0.5768

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 15		
Number of subjects with a response, n (%) [2]	7 (21.9)	11 (35.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.616
95% CI for the RR		(0.730, 3.577)
p-value for RR		0.2369
Day 21		
Number of subjects with a response, n (%) [2]	13 (40.6)	11 (35.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.870
95% CI for the RR		(0.463, 1.633)
p-value for RR		0.6647

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 45		
Number of subjects with a response, n (%) [2]	18 (56.3)	20 (64.5)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.142
95% CI for the RR		(0.768, 1.699)
p-value for RR		0.5109

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 3		
Number of subjects with a response, n (%) [2]	3 (7.5)	8 (18.2)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		2.202
95% CI for the RR		(0.631, 7.687)
p-value for RR		0.2160
Day 8		
Number of subjects with a response, n (%) [2]	11 (27.5)	17 (38.6)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.276
95% CI for the RR		(0.696, 2.341)
p-value for RR		0.4311

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	11 (27.5)	24 (54.5)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.801
95% CI for the RR		(1.021, 3.179)
p-value for RR		0.0423
Day 21		
Number of subjects with a response, n (%) [2]	20 (50.0)	24 (54.5)
Number of subjects with missing evaluation, n (%)	1 (2.5)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.991
95% CI for the RR		(0.672, 1.461)
p-value for RR		0.9627

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 6 of 6

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	17 (42.5)	29 (65.9)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.408
95% CI for the RR		(0.913, 2.173)
p-value for RR		0.1216

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

3.1.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 6

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 3		
Number of subjects with a response, n (%) [2]	1 (7.7)	1 (6.3)
Number of subjects with missing evaluation, n (%)	0	2 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.846
95% CI for the RR		(0.060, 11.945)
p-value for RR		0.9013
Day 8		
Number of subjects with a response, n (%) [2]	3 (23.1)	7 (43.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.973
95% CI for the RR		(0.657, 5.927)
p-value for RR		0.2258

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 15		
Number of subjects with a response, n (%) [2]	4 (30.8)	10 (62.5)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.114
95% CI for the RR		(0.844, 5.299)
p-value for RR		0.1103
Day 21		
Number of subjects with a response, n (%) [2]	7 (53.8)	9 (56.3)
Number of subjects with missing evaluation, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.087
95% CI for the RR		(0.544, 2.172)
p-value for RR		0.8126

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 45		
Number of subjects with a response, n (%) [2]	5 (38.5)	10 (62.5)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.691
95% CI for the RR		(0.713, 4.010)
p-value for RR		0.2328

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 3		
Number of subjects with a response, n (%) [2]	6 (9.7)	10 (16.7)
Number of subjects with missing evaluation, n (%)	3 (4.8)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.612
95% CI for the RR		(0.634, 4.100)
p-value for RR		0.3158
Day 8		
Number of subjects with a response, n (%) [2]	16 (25.8)	16 (26.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.967
95% CI for the RR		(0.546, 1.714)
p-value for RR		0.9095

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 15		
Number of subjects with a response, n (%) [2]	16 (25.8)	25 (41.7)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.512
95% CI for the RR		(0.906, 2.522)
p-value for RR		0.1136
Day 21		
Number of subjects with a response, n (%) [2]	28 (45.2)	26 (43.3)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.898
95% CI for the RR		(0.609, 1.325)
p-value for RR		0.5883

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 45		
Number of subjects with a response, n (%) [2]	32 (51.6)	39 (65.0)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.179
95% CI for the RR		(0.864, 1.609)
p-value for RR		0.2996

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

3.1.2.1 .2 .2 .5 BMI

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 3		
Number of subjects with a response, n (%) [2]	3 (14.3)	2 (15.4)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.981
95% CI for the RR		(0.194, 4.955)
p-value for RR		0.9813
Day 8		
Number of subjects with a response, n (%) [2]	7 (33.3)	3 (23.1)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.631
95% CI for the RR		(0.207, 1.919)
p-value for RR		0.4167

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 15		
Number of subjects with a response, n (%) [2]	5 (23.8)	6 (46.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.765
95% CI for the RR		(0.680, 4.585)
p-value for RR		0.2431
Day 21		
Number of subjects with a response, n (%) [2]	8 (38.1)	7 (53.8)
Number of subjects with missing evaluation, n (%)	2 (9.5)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.287
95% CI for the RR		(0.646, 2.566)
p-value for RR		0.4730

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 45		
Number of subjects with a response, n (%) [2]	6 (28.6)	7 (53.8)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.716
95% CI for the RR		(0.758, 3.886)
p-value for RR		0.1951

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 3		
Number of subjects with a response, n (%) [2]	3 (15.0)	4 (19.0)
Number of subjects with missing evaluation, n (%)	1 (5.0)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.246
95% CI for the RR		(0.316, 4.912)
p-value for RR		0.7535
Day 8		
Number of subjects with a response, n (%) [2]	4 (20.0)	8 (38.1)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.869
95% CI for the RR		(0.690, 5.064)
p-value for RR		0.2189

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	6 (30.0)	9 (42.9)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.402
95% CI for the RR		(0.639, 3.076)
p-value for RR		0.4000
Day 21		
Number of subjects with a response, n (%) [2]	12 (60.0)	10 (47.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.779
95% CI for the RR		(0.439, 1.382)
p-value for RR		0.3926

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 45		
Number of subjects with a response, n (%) [2]	12 (60.0)	12 (57.1)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.934
95% CI for the RR		(0.568, 1.537)
p-value for RR		0.7893

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 3		
Number of subjects with a response, n (%) [2]	1 (2.9)	5 (11.9)
Number of subjects with missing evaluation, n (%)	1 (2.9)	3 (7.1)
RR - Relative Risk (Zuranolone vs. Placebo)		3.831
95% CI for the RR		(0.463, 31.674)
p-value for RR		0.2127
Day 8		
Number of subjects with a response, n (%) [2]	8 (23.5)	12 (28.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.149
95% CI for the RR		(0.539, 2.452)
p-value for RR		0.7191

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 15		
Number of subjects with a response, n (%) [2]	9 (26.5)	20 (47.6)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.703
95% CI for the RR		(0.893, 3.247)
p-value for RR		0.1063
Day 21		
Number of subjects with a response, n (%) [2]	15 (44.1)	18 (42.9)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.919
95% CI for the RR		(0.553, 1.530)
p-value for RR		0.7462

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 45		
Number of subjects with a response, n (%) [2]	19 (55.9)	30 (71.4)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.210
95% CI for the RR		(0.840, 1.742)
p-value for RR		0.3064

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

3.1.2.1 .2 .2 .6 Beginn der PPD

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 3		
Number of subjects with a response, n (%) [2]	2 (6.3)	6 (18.8)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.039
95% CI for the RR		(0.675, 13.680)
p-value for RR		0.1475
Day 8		
Number of subjects with a response, n (%) [2]	8 (25.0)	7 (21.9)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.887
95% CI for the RR		(0.376, 2.089)
p-value for RR		0.7830

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 6

Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 15		
Number of subjects with a response, n (%) [2]	7 (21.9)	12 (37.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.737
95% CI for the RR		(0.787, 3.835)
p-value for RR		0.1720
Day 21		
Number of subjects with a response, n (%) [2]	16 (50.0)	12 (37.5)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.760
95% CI for the RR		(0.440, 1.313)
p-value for RR		0.3249

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 45		
Number of subjects with a response, n (%) [2]	19 (59.4)	19 (59.4)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.013
95% CI for the RR		(0.668, 1.538)
p-value for RR		0.9510

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 3		
Number of subjects with a response, n (%) [2]	5 (11.6)	5 (11.4)
Number of subjects with missing evaluation, n (%)	2 (4.7)	4 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.864
95% CI for the RR		(0.271, 2.759)
p-value for RR		0.8056
Day 8		
Number of subjects with a response, n (%) [2]	11 (25.6)	16 (36.4)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.257
95% CI for the RR		(0.676, 2.339)
p-value for RR		0.4699

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	13 (30.2)	23 (52.3)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.529
95% CI for the RR		(0.899, 2.602)
p-value for RR		0.1174
Day 21		
Number of subjects with a response, n (%) [2]	19 (44.2)	23 (52.3)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.046
95% CI for the RR		(0.676, 1.619)
p-value for RR		0.8390

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	18 (41.9)	30 (68.2)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.441
95% CI for the RR		(0.945, 2.196)
p-value for RR		0.0897

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

3.1.2.1 .2 .2 .7 PPD in der Familie

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 3		
Number of subjects with a response, n (%) [2]	1 (10.0)	1 (10.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.179
95% CI for the RR		(0.089, 15.649)
p-value for RR		0.9007
Day 8		
Number of subjects with a response, n (%) [2]	5 (50.0)	1 (10.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.236
95% CI for the RR		(0.033, 1.695)
p-value for RR		0.1511

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	4 (40.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.179
95% CI for the RR		(0.369, 3.767)
p-value for RR		0.7812
Day 21		
Number of subjects with a response, n (%) [2]	6 (60.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.786
95% CI for the RR		(0.290, 2.131)
p-value for RR		0.6360

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	6 (60.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.179
95% CI for the RR		(0.561, 2.479)
p-value for RR		0.6642

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 3		
Number of subjects with a response, n (%) [2]	6 (9.2)	10 (15.2)
Number of subjects with missing evaluation, n (%)	3 (4.6)	4 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.501
95% CI for the RR		(0.583, 3.861)
p-value for RR		0.3998
Day 8		
Number of subjects with a response, n (%) [2]	14 (21.5)	22 (33.3)
Number of subjects with missing evaluation, n (%)	1 (1.5)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.415
95% CI for the RR		(0.802, 2.496)
p-value for RR		0.2309

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	16 (24.6)	31 (47.0)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.745
95% CI for the RR		(1.060, 2.871)
p-value for RR		0.0286
Day 21		
Number of subjects with a response, n (%) [2]	29 (44.6)	31 (47.0)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.962
95% CI for the RR		(0.662, 1.400)
p-value for RR		0.8414

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	31 (47.7)	43 (65.2)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.249
95% CI for the RR		(0.903, 1.728)
p-value for RR		0.1797

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

3.1.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 3		
Number of subjects with a response, n (%) [2]	7 (11.9)	9 (13.6)
Number of subjects with missing evaluation, n (%)	1 (1.7)	4 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.15
95% CI for the RR		(0.457, 2.893)
p-value for RR		0.7676
Day 8		
Number of subjects with a response, n (%) [2]	16 (27.1)	20 (30.3)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.12
95% CI for the RR		(0.641, 1.948)
p-value for RR		0.6954

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	17 (28.8)	31 (47.0)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.63
95% CI for the RR		(1.013, 2.624)
p-value for RR		0.0442
Day 21		
Number of subjects with a response, n (%) [2]	28 (47.5)	30 (45.5)
Number of subjects with missing evaluation, n (%)	1 (1.7)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.96
95% CI for the RR		(0.657, 1.396)
p-value for RR		0.8225

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	30 (50.8)	42 (63.6)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.25
95% CI for the RR		(0.918, 1.707)
p-value for RR		0.1563

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 3		
Number of subjects with a response, n (%) [2]	0	2 (20.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		7.73
95% CI for the RR		(0.408, 146.186)
p-value for RR		0.1729
Day 8		
Number of subjects with a response, n (%) [2]	3 (18.8)	3 (30.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.60
95% CI for the RR		(0.398, 6.434)
p-value for RR		0.5080

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	3 (18.8)	4 (40.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.13
95% CI for the RR		(0.598, 7.608)
p-value for RR		0.2428
Day 21		
Number of subjects with a response, n (%) [2]	7 (43.8)	5 (50.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.14
95% CI for the RR		(0.497, 2.627)
p-value for RR		0.7532

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-201-by.sas:t-bimf-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	7 (43.8)	7 (70.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.60
95% CI for the RR		(0.804, 3.184)
p-value for RR		0.1806

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response (18 points (15% of total scale range 0-120) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

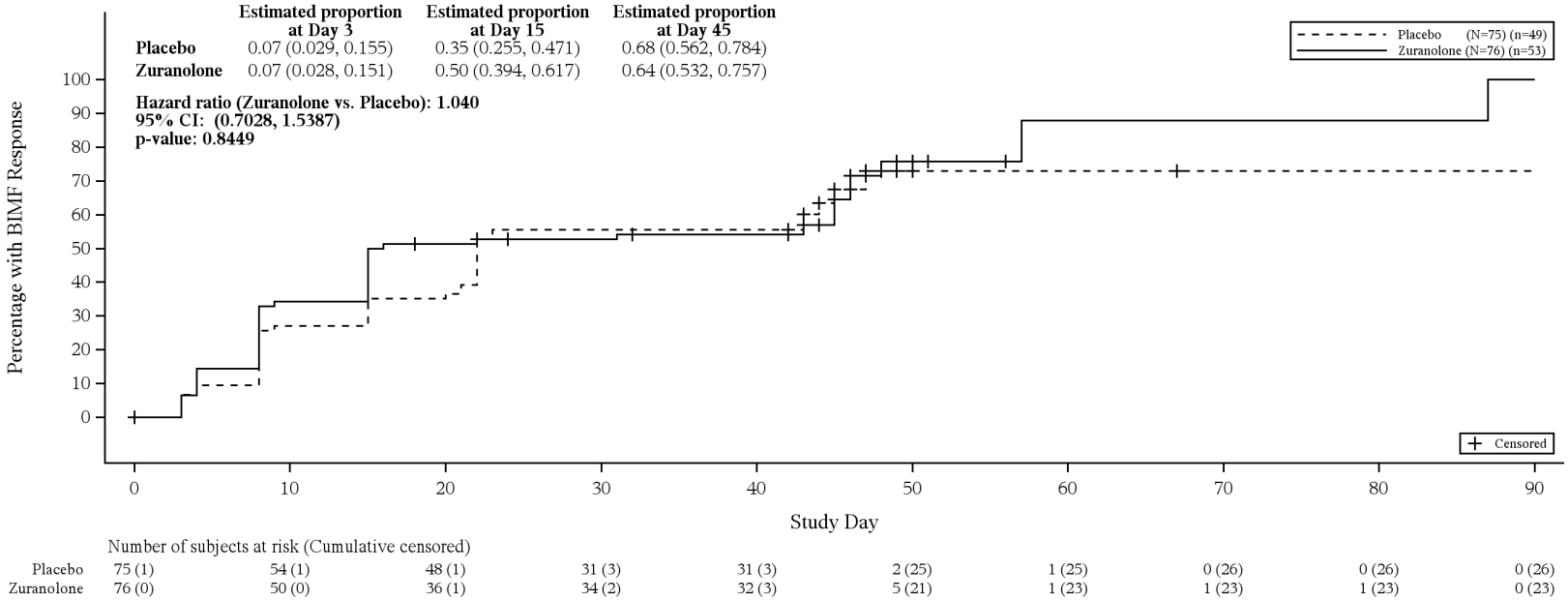
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3.1.2.2 TTE-Analysen

3.1.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-ovr.sas:f-bimf-resp15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	49 (65.3)	53 (69.7)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 15.0)	8.0 (8.0 , 15.0)
50th percentile - median (95% CI)	22.0 (21.0 , 44.0)	15.5 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	48.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.040
95% CI for the HR		(0.7028 , 1.5387)
p-value for the HR		0.8449

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-ovr.sas:t-bimf-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.1.2.2 .2 Subgruppen

3.1.2.2 .2 .1 Interaktionstest

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	49 (65.3)	53 (69.7)	
Age Group (years)			
18 - 24, n / N (%)	16/25 (64.0)	11/17 (64.7)	0.5662
25 - 45, n / N (%)	33/50 (66.0)	42/59 (71.2)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	16/22 (72.7)	21/30 (70.0)	0.3352
>=28, n / N (%)	33/53 (62.3)	32/46 (69.6)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	23/32 (71.9)	20/31 (64.5)	0.0407
White, n / N (%)	24/40 (60.0)	32/44 (72.7)	
Antidepressant Use at Baseline			
Yes, n / N (%)	9/13 (69.2)	12/16 (75.0)	0.4783
No, n / N (%)	40/62 (64.5)	41/60 (68.3)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-int.sas:t-bimf-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	11/21 (52.4)	8/13 (61.5)	0.5878(a)
25-29.9, n / N (%)	15/20 (75.0)	12/21 (57.1)	0.7743(b)
>=30, n / N (%)	23/34 (67.6)	33/42 (78.6)	0.7183(c)
Onset of PPD			
3rd Trimester, n / N (%)	25/32 (78.1)	21/32 (65.6)	0.0711
Postpartum, n / N (%)	24/43 (55.8)	32/44 (72.7)	
Family History of PPD			
Yes, n / N (%)	8/10 (80.0)	6/10 (60.0)	0.2804
No/Unknown, n / N (%)	41/65 (63.1)	47/66 (71.2)	
History of PPD			
1st Episode, n / N (%)	38/59 (64.4)	46/66 (69.7)	0.7903
Recurrent Episode, n / N (%)	11/16 (68.8)	7/10 (70.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	7/8 (87.5)	8/10 (80.0)	NA
>=20, n / N (%)	42/67 (62.7)	45/66 (68.2)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-int.sas:t-bimf-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

3.1.2.2 .2 .2 Subgruppenanalysen

3.1.2.2 .2 .2 .1 Alter

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	16 (64.0)	11 (64.7)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 22.0)	8.0 (3.0 , 15.0)
50th percentile - median (95% CI)	22.0 (9.0, NE)	22.0 (8.0, NE)
75th percentile - Q3 (95% CI)	NE (43.0, NE)	87.0 (22.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.758
95% CI for the HR		(0.3256 , 1.7649)
p-value for the HR		0.5206

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	33 (66.0)	42 (71.2)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 21.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	22.0 (20.0 , 44.0)	15.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	47.0 (44.0, NE)	48.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.073
95% CI for the HR		(0.6775 , 1.7007)
p-value for the HR		0.7627

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

3.1.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	16 (72.7)	21 (70.0)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (3.0 , 21.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	22.0 (9.0 , 23.0)	15.0 (8.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	46.0 (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.752
95% CI for the HR		(0.3788 , 1.4920)
p-value for the HR		0.4146

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	33 (62.3)	32 (69.6)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 21.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	43.0 (21.0 , 45.0)	19.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	87.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.147
95% CI for the HR		(0.7012 , 1.8763)
p-value for the HR		0.5848

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

3.1.2.2 .2 .2 .3 Abstammung

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	23 (71.9)	20 (64.5)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 22.0)	15.0 (8.0 , 45.0)
50th percentile - median (95% CI)	22.0 (15.0 , 44.0)	45.0 (15.0 , 57.0)
75th percentile - Q3 (95% CI)	45.0 (43.0, NE)	57.0 (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.584
95% CI for the HR		(0.3106 , 1.0985)
p-value for the HR		0.0952

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	24 (60.0)	32 (72.7)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 22.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	22.5 (15.0, NE)	15.0 (8.0 , 43.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	48.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.418
95% CI for the HR		(0.8315 , 2.4184)
p-value for the HR		0.1997

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

3.1.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	9 (69.2)	12 (75.0)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (3.0 , 22.0)	8.0 (3.0 , 15.0)
50th percentile - median (95% CI)	22.0 (8.0, NE)	15.0 (8.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.328
95% CI for the HR		(0.5517 , 3.1975)
p-value for the HR		0.5266

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	40 (64.5)	41 (68.3)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 20.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	22.0 (21.0 , 44.0)	31.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (44.0, NE)	57.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.963
95% CI for the HR		(0.6191 , 1.4973)
p-value for the HR		0.8664

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

3.1.2.2 .2 .2 .5 BMI

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	11 (52.4)	8 (61.5)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 22.0)	15.0 (3.0 , 31.0)
50th percentile - median (95% CI)	22.5 (8.0, NE)	31.0 (8.0, NE)
75th percentile - Q3 (95% CI)	NE (23.0, NE)	46.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.089
95% CI for the HR		(0.4350 , 2.7260)
p-value for the HR		0.8556

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	15 (75.0)	12 (57.1)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 22.0)	8.0 (3.0 , 15.0)
50th percentile - median (95% CI)	22.0 (15.0 , 43.0)	45.0 (8.0, NE)
75th percentile - Q3 (95% CI)	45.0 (22.0, NE)	NE (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.906
95% CI for the HR		(0.4170 , 1.9669)
p-value for the HR		0.8022

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	23 (67.6)	33 (78.6)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 22.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	23.0 (15.0 , 45.0)	15.0 (9.0 , 45.0)
75th percentile - Q3 (95% CI)	47.0 (44.0, NE)	48.0 (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.025
95% CI for the HR		(0.5887 , 1.7850)
p-value for the HR		0.9301

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

3.1.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	25 (78.1)	21 (65.6)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (8.0 , 21.0)	8.0 (3.0 , 15.0)
50th percentile - median (95% CI)	22.0 (15.0 , 43.0)	45.0 (15.0 , 57.0)
75th percentile - Q3 (95% CI)	44.0 (22.0, NE)	57.0 (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.639
95% CI for the HR		(0.3378 , 1.2074)
p-value for the HR		0.1676

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	24 (55.8)	32 (72.7)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 22.0)	8.0 (4.0 , 9.0)
50th percentile - median (95% CI)	43.0 (15.0, NE)	15.0 (8.0 , 43.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	46.0 (31.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.370
95% CI for the HR		(0.7932 , 2.3651)
p-value for the HR		0.2591

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

3.1.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	8 (80.0)	6 (60.0)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 15.0)	15.0 (3.0 , 43.0)
50th percentile - median (95% CI)	11.5 (3.0 , 23.0)	43.0 (3.0, NE)
75th percentile - Q3 (95% CI)	23.0 (8.0, NE)	48.0 (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.636
95% CI for the HR		(0.1782 , 2.2695)
p-value for the HR		0.4855

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	41 (63.1)	47 (71.2)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 21.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	22.5 (22.0 , 45.0)	15.0 (9.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	57.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.162
95% CI for the HR		(0.7574 , 1.7826)
p-value for the HR		0.4917

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

3.1.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	38 (64.4)	46 (69.7)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 22.0)	8.0 (8.0 , 15.0)
50th percentile - median (95% CI)	22.0 (22.0 , 44.0)	15.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	87.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.046
95% CI for the HR		(0.6766 , 1.6179)
p-value for the HR		0.8387

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-resp15-tte-201-by.sas:t-bimf-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	11 (68.8)	7 (70.0)
Time to first BIMF response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 21.0)	8.0 (3.0 , 22.0)
50th percentile - median (95% CI)	21.0 (8.0 , 47.0)	22.0 (3.0, NE)
75th percentile - Q3 (95% CI)	47.0 (21.0, NE)	48.0 (22.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.697
95% CI for the HR		(0.2214 , 2.1913)
p-value for the HR		0.5363

NOTE 1: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF total score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.

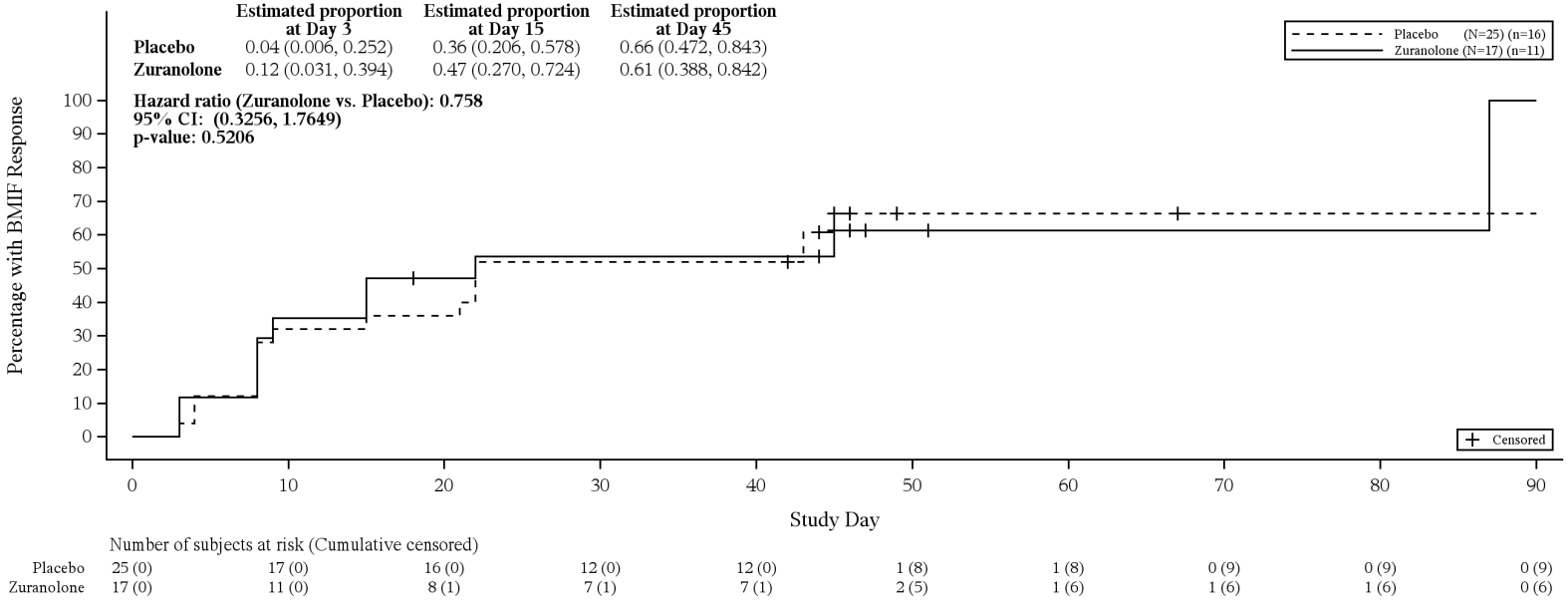
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3.1.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

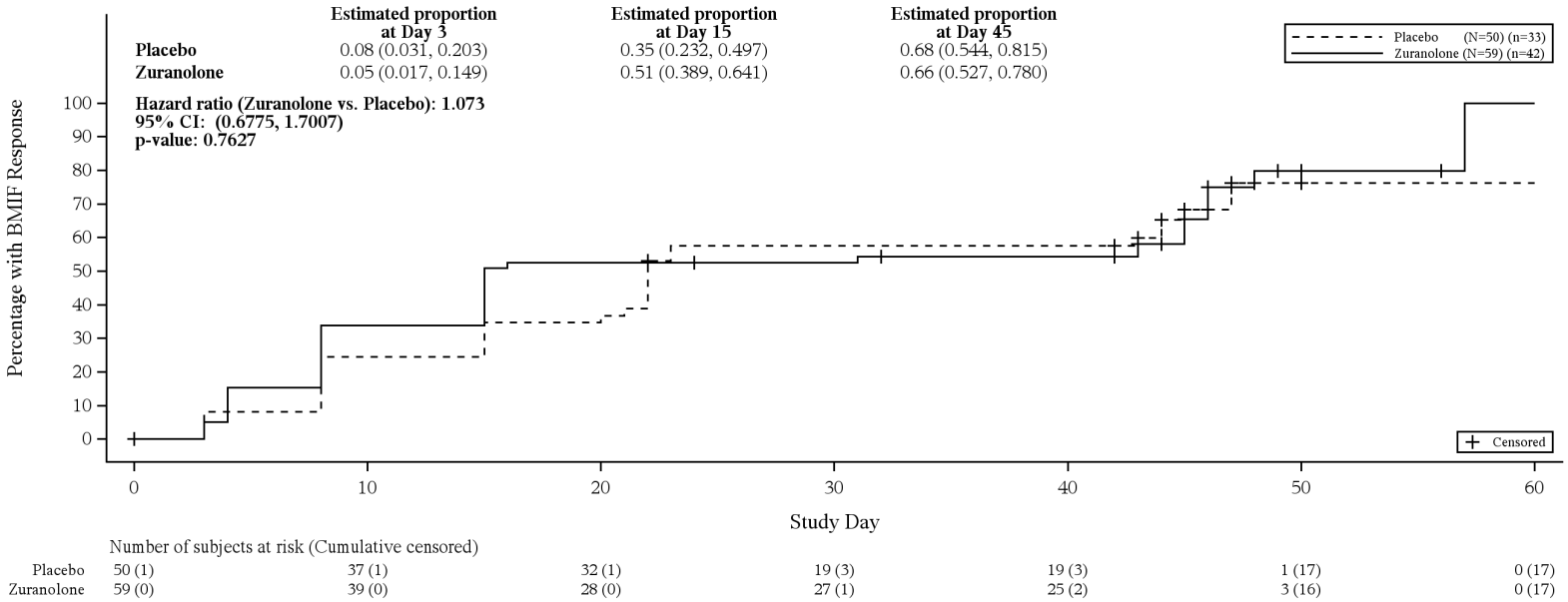
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Number of subjects at risk (Cumulative censored)

Placebo	50 (1)	37 (1)	32 (1)	19 (3)	19 (3)	1 (17)	0 (17)
Zuranolone	59 (0)	39 (0)	28 (0)	27 (1)	25 (2)	3 (16)	0 (17)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

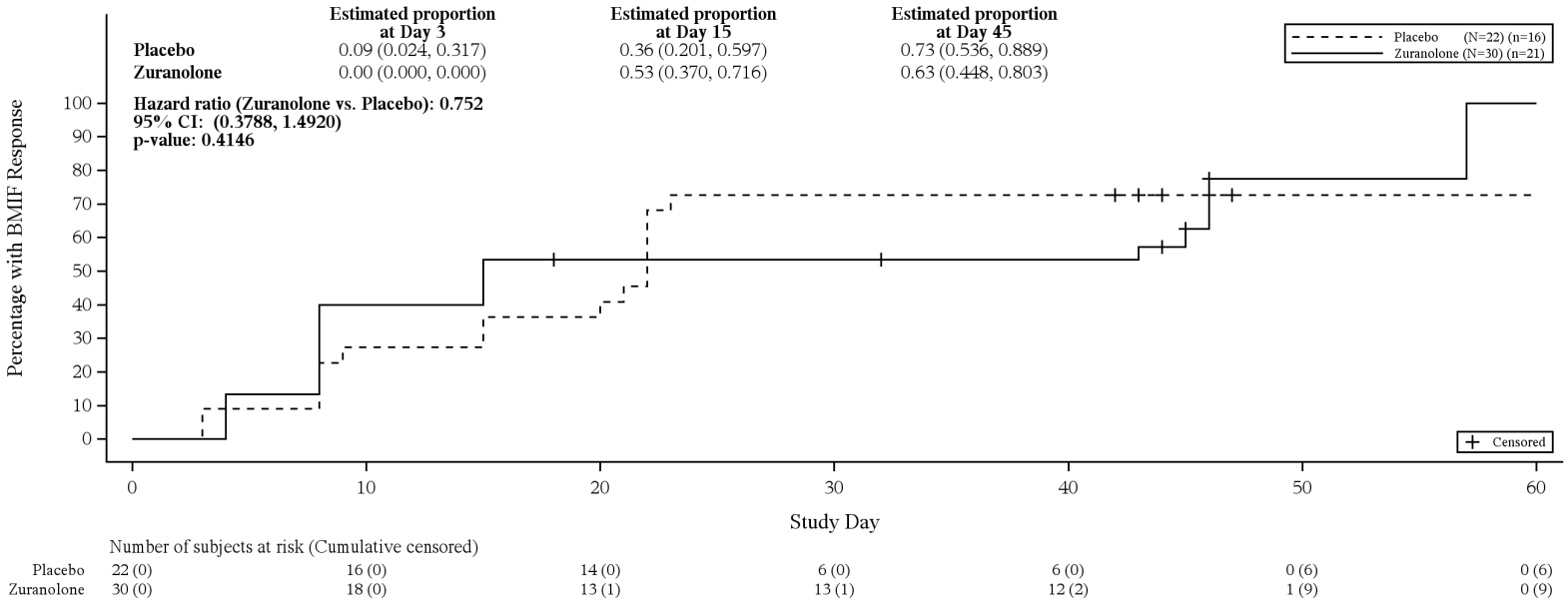
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	16 (0)	14 (0)	6 (0)	6 (0)	0 (6)	0 (6)
Zuranolone	30 (0)	18 (0)	13 (1)	13 (1)	12 (2)	1 (9)	0 (9)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

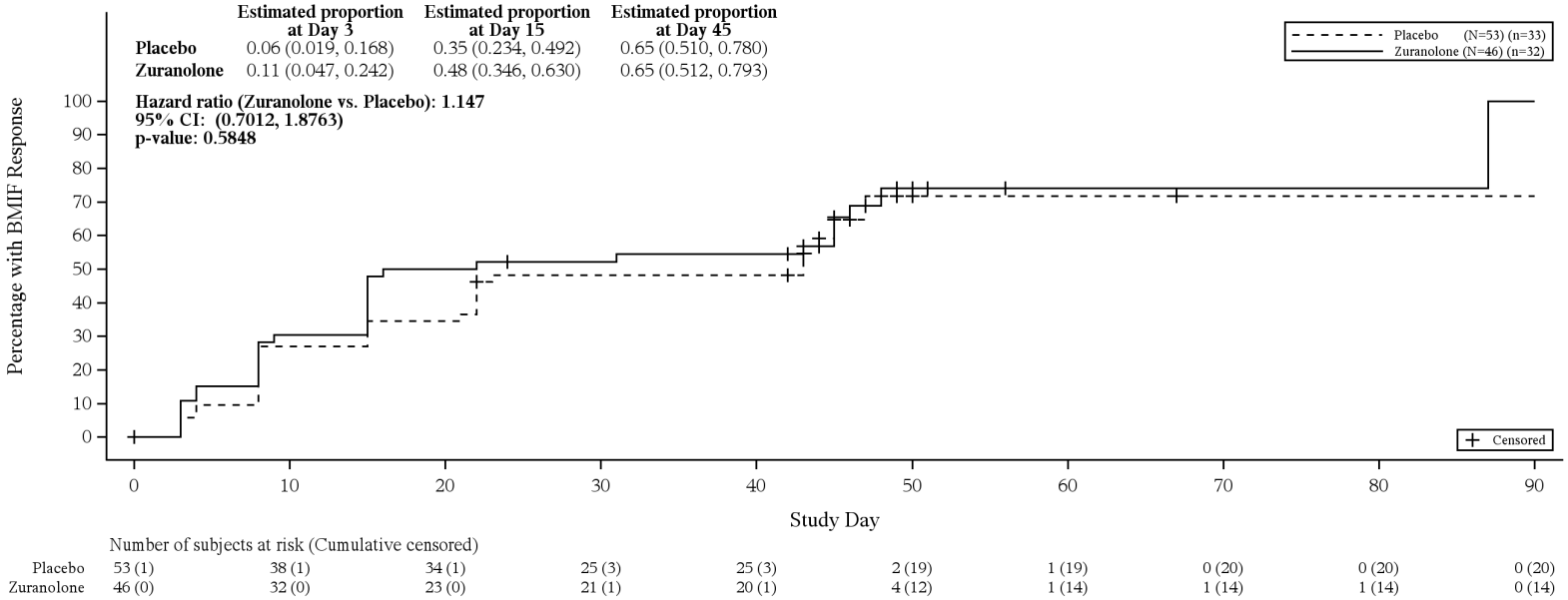
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

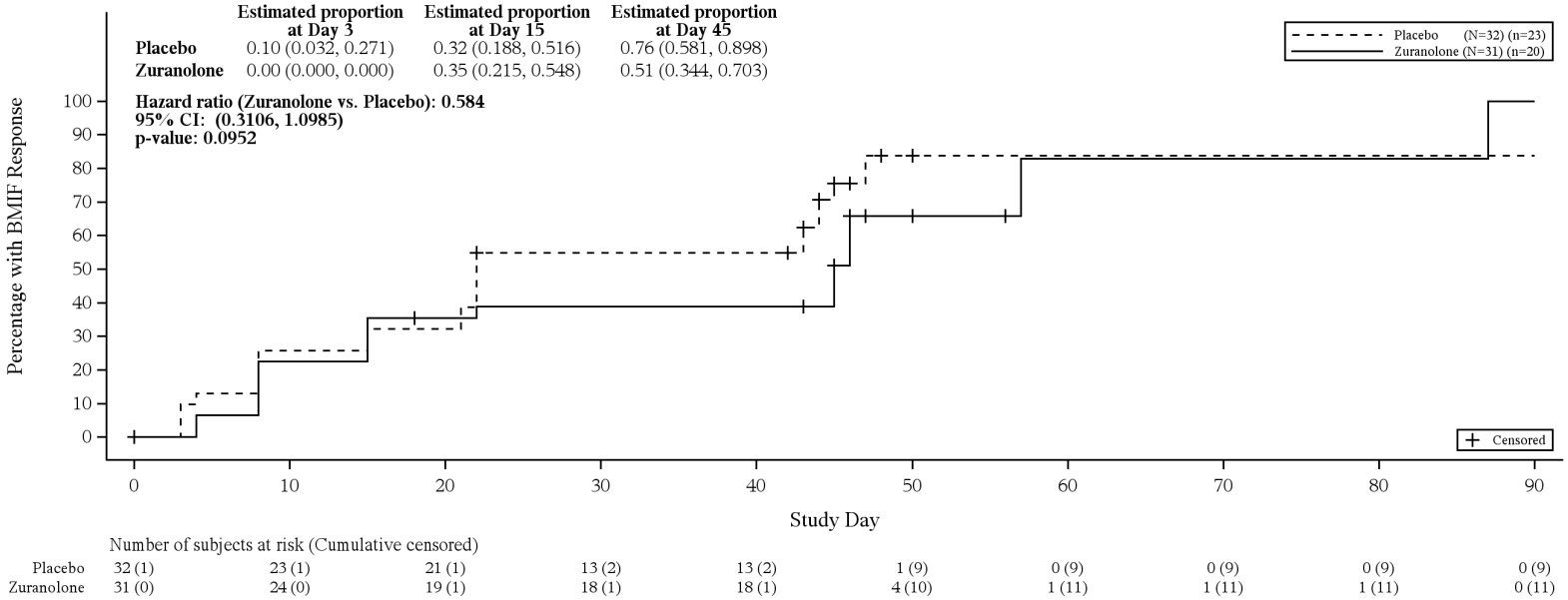
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

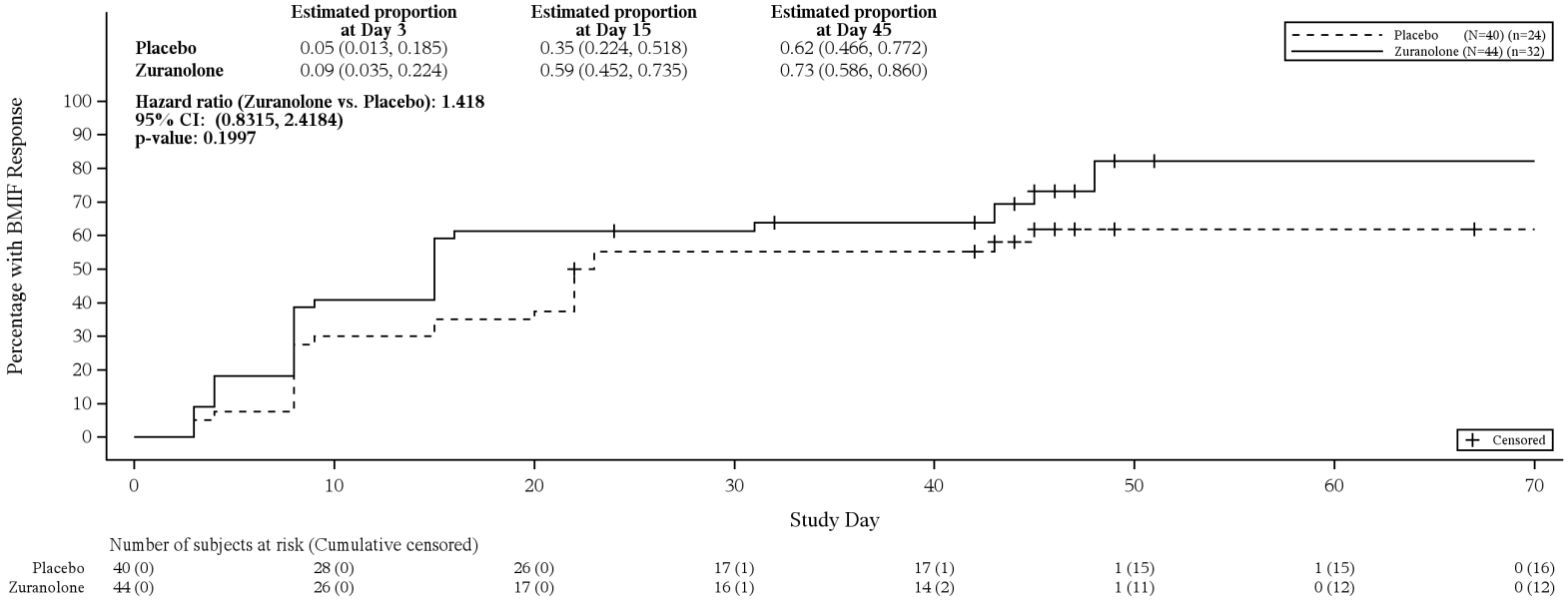
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Number of subjects at risk (Cumulative censored)

Placebo	40 (0)	28 (0)	26 (0)	17 (1)	17 (1)	1 (15)	1 (15)	0 (16)
Zuranolone	44 (0)	26 (0)	17 (0)	16 (1)	14 (2)	1 (11)	0 (12)	0 (12)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

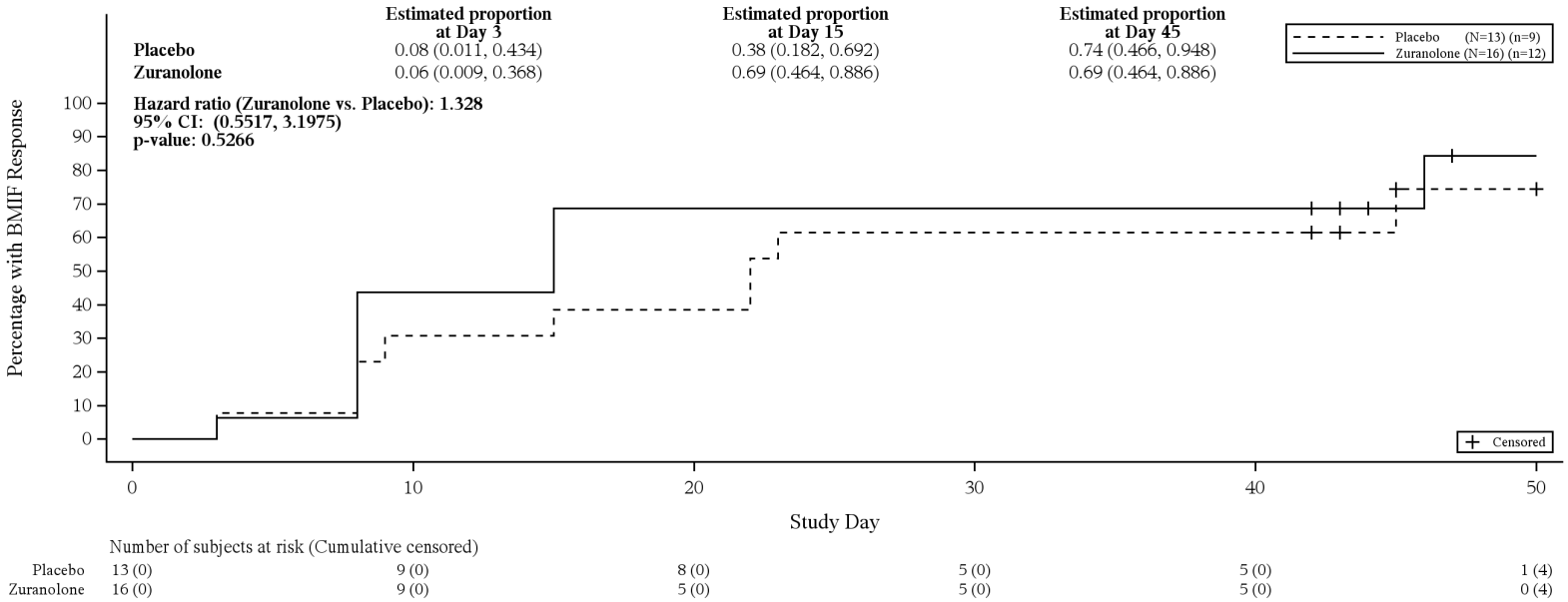
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	13 (0)	9 (0)	8 (0)	5 (0)	5 (0)	1 (4)
Zuranolone	16 (0)	9 (0)	5 (0)	5 (0)	5 (0)	0 (4)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

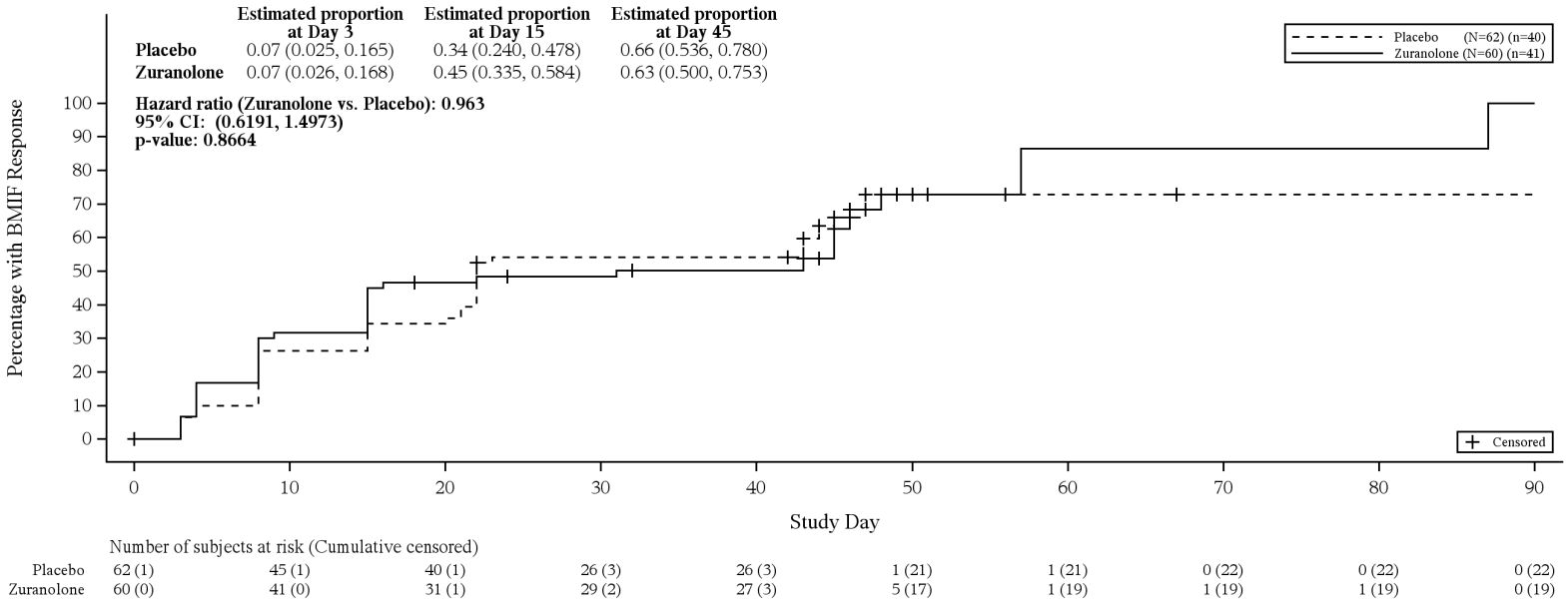
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

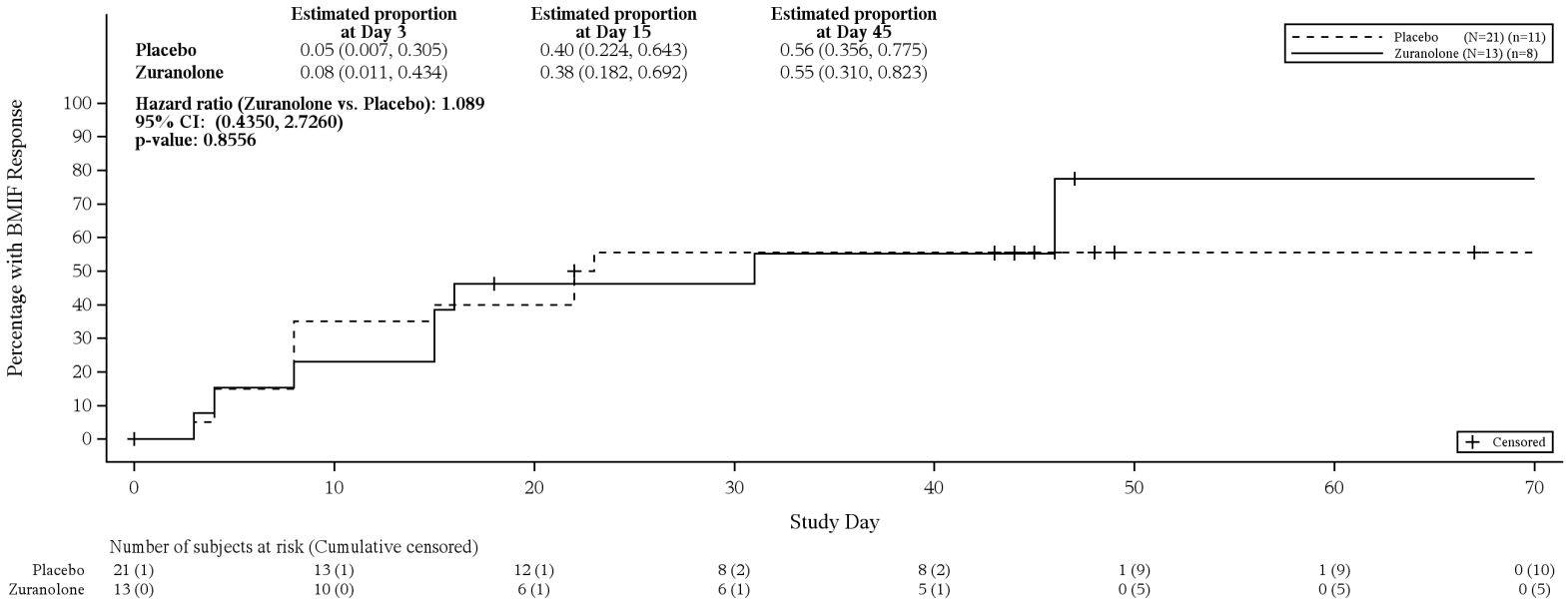
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Number of subjects at risk (Cumulative censored)

Placebo	21 (1)	13 (1)	12 (1)	8 (2)	8 (2)	1 (9)	1 (9)	0 (10)
Zuranolone	13 (0)	10 (0)	6 (1)	6 (1)	5 (1)	0 (5)	0 (5)	0 (5)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

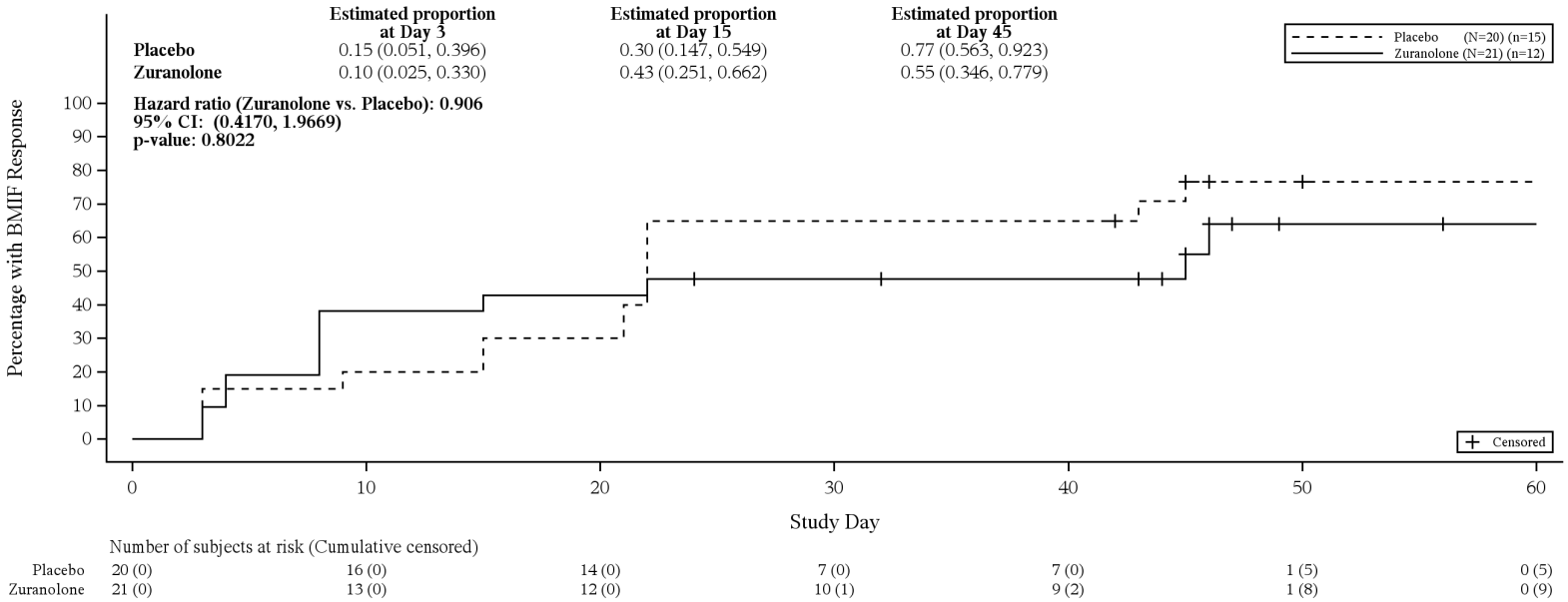
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Number of subjects at risk (Cumulative censored)

Placebo	20 (0)	16 (0)	14 (0)	7 (0)	7 (0)	1 (5)	0 (5)
Zuranolone	21 (0)	13 (0)	12 (0)	10 (1)	9 (2)	1 (8)	0 (9)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

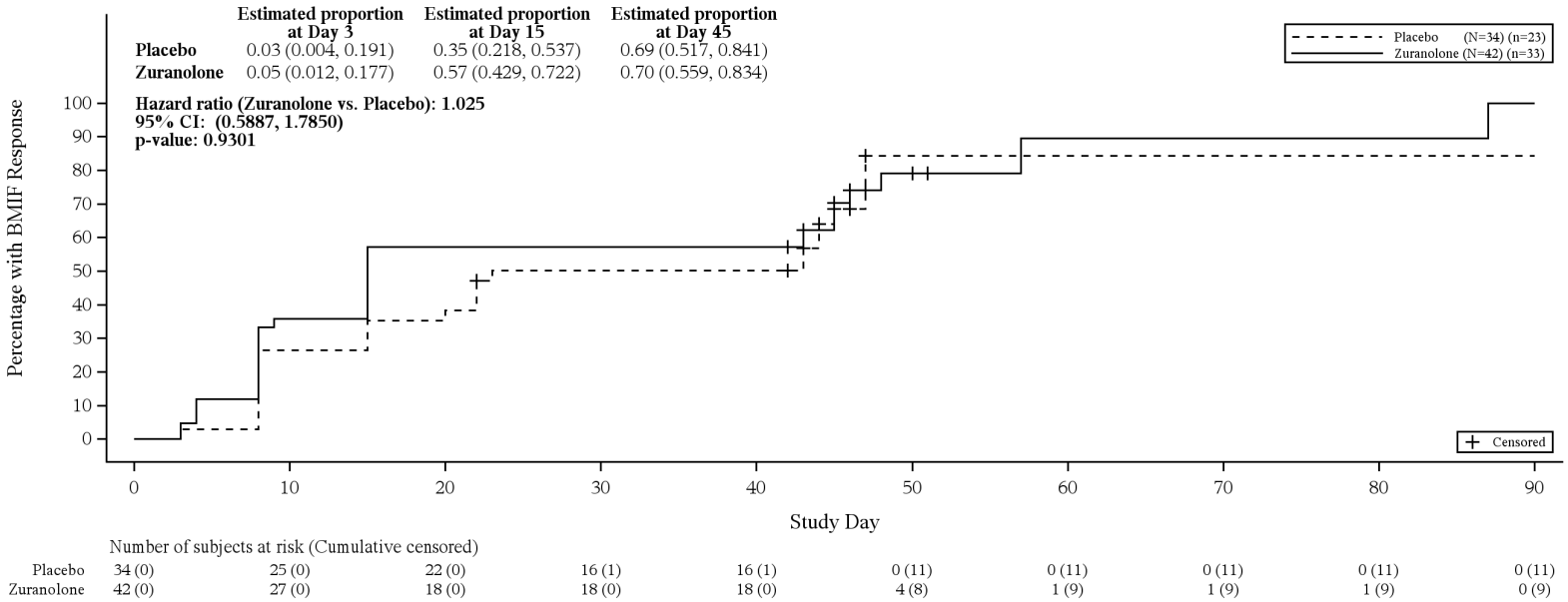
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Number of subjects at risk (Cumulative censored)

Placebo	34 (0)	25 (0)	22 (0)	16 (1)	16 (1)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)
Zuranolone	42 (0)	27 (0)	18 (0)	18 (0)	18 (0)	4 (8)	1 (9)	1 (9)	1 (9)	0 (9)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

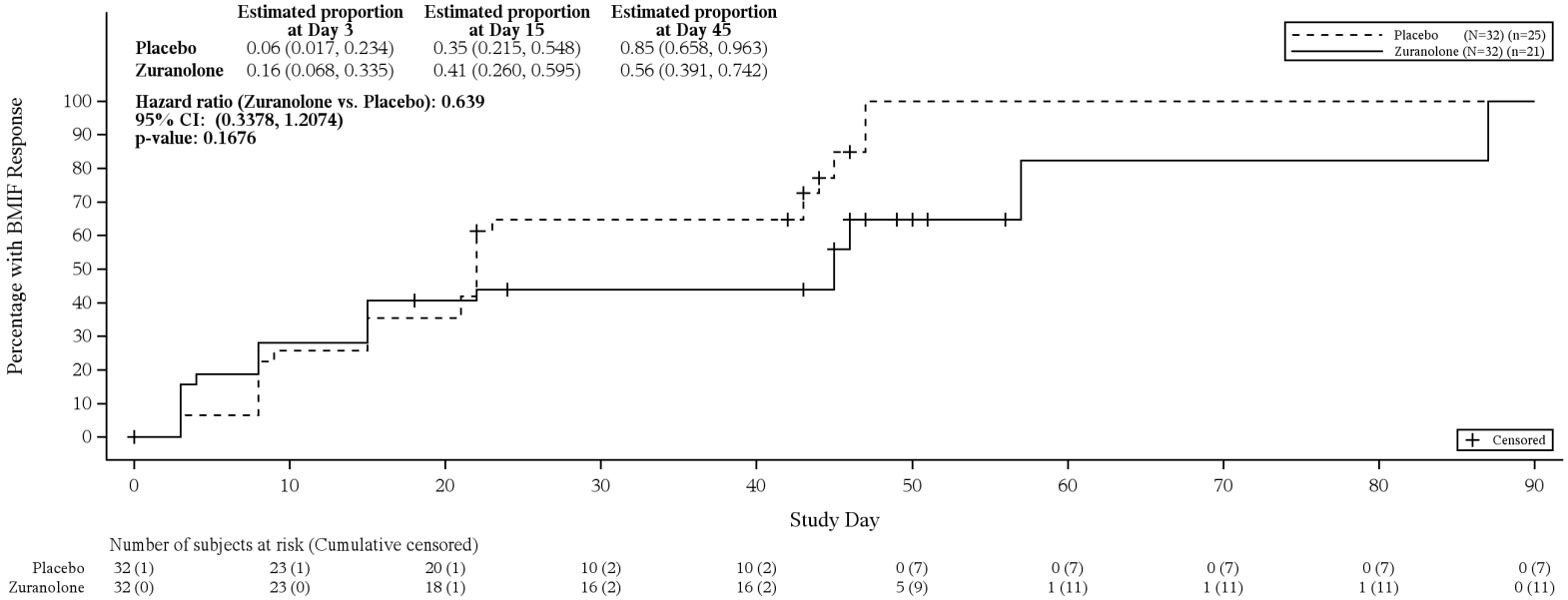
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

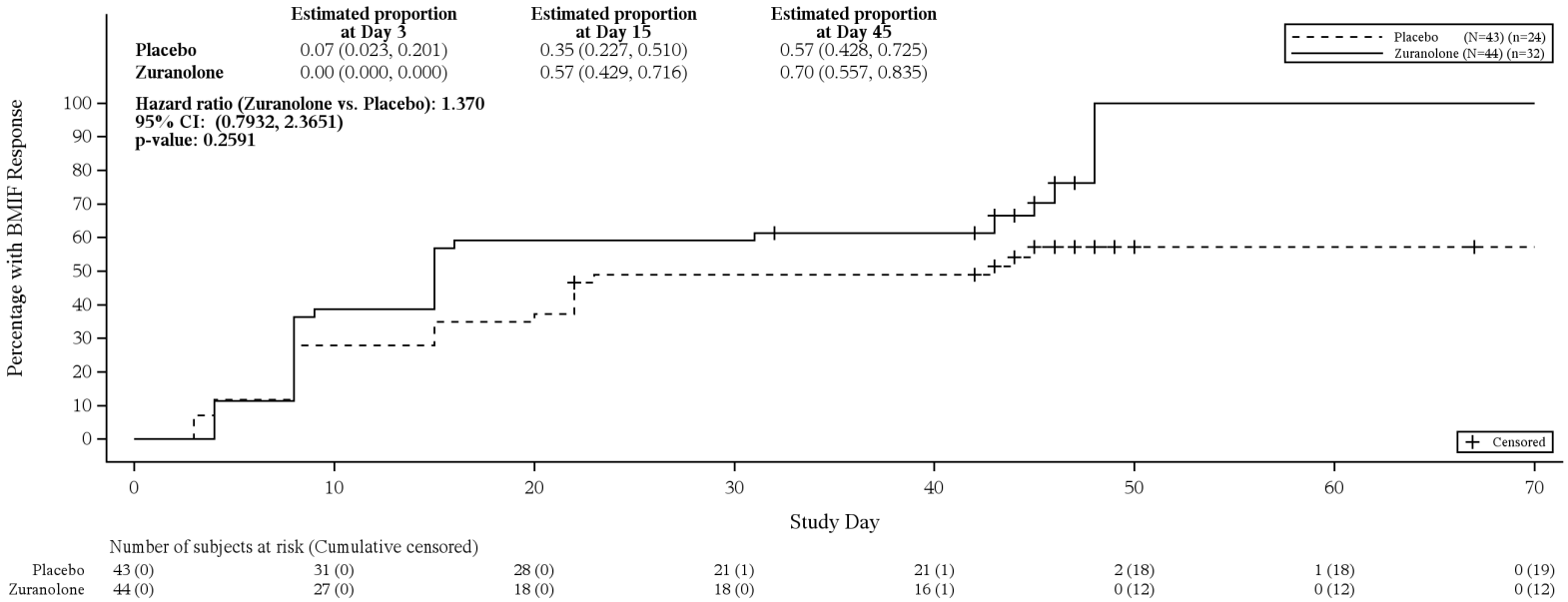
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

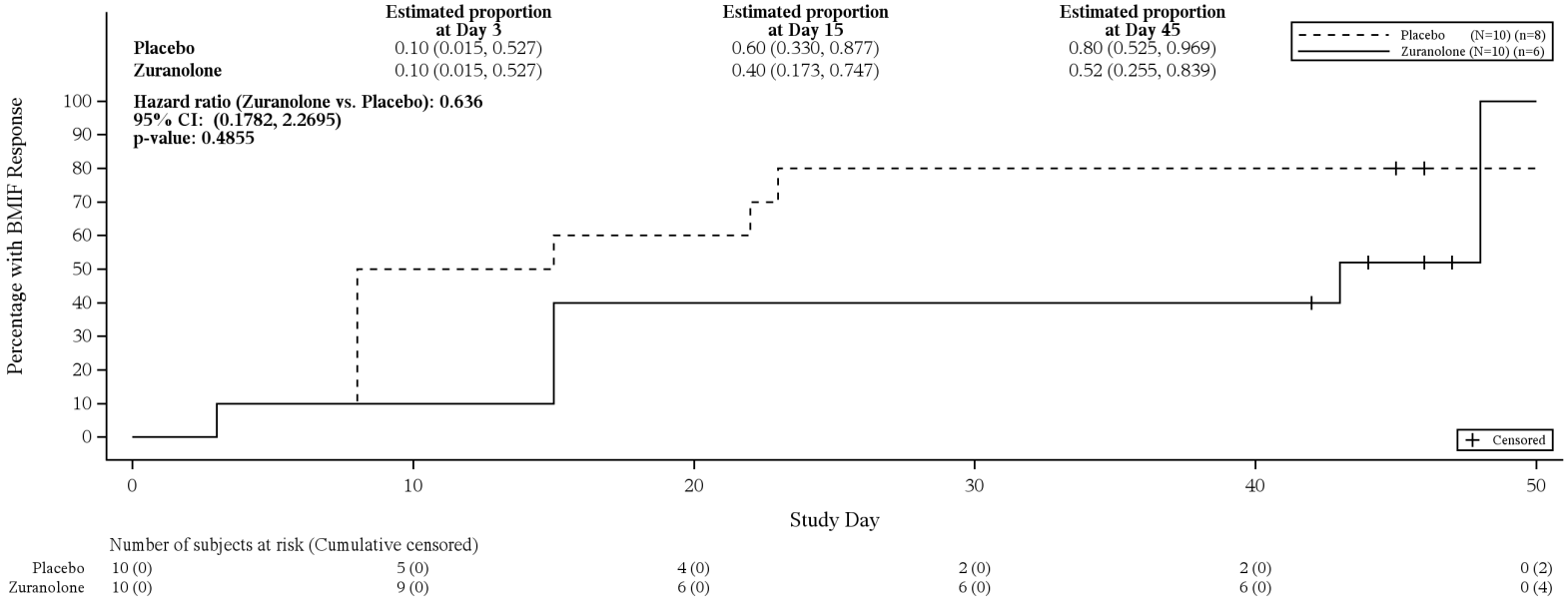
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Number of subjects at risk (Cumulative censored)

Placebo	10 (0)	5 (0)	4 (0)	2 (0)	2 (0)	0 (2)
Zuranolone	10 (0)	9 (0)	6 (0)	6 (0)	6 (0)	0 (4)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

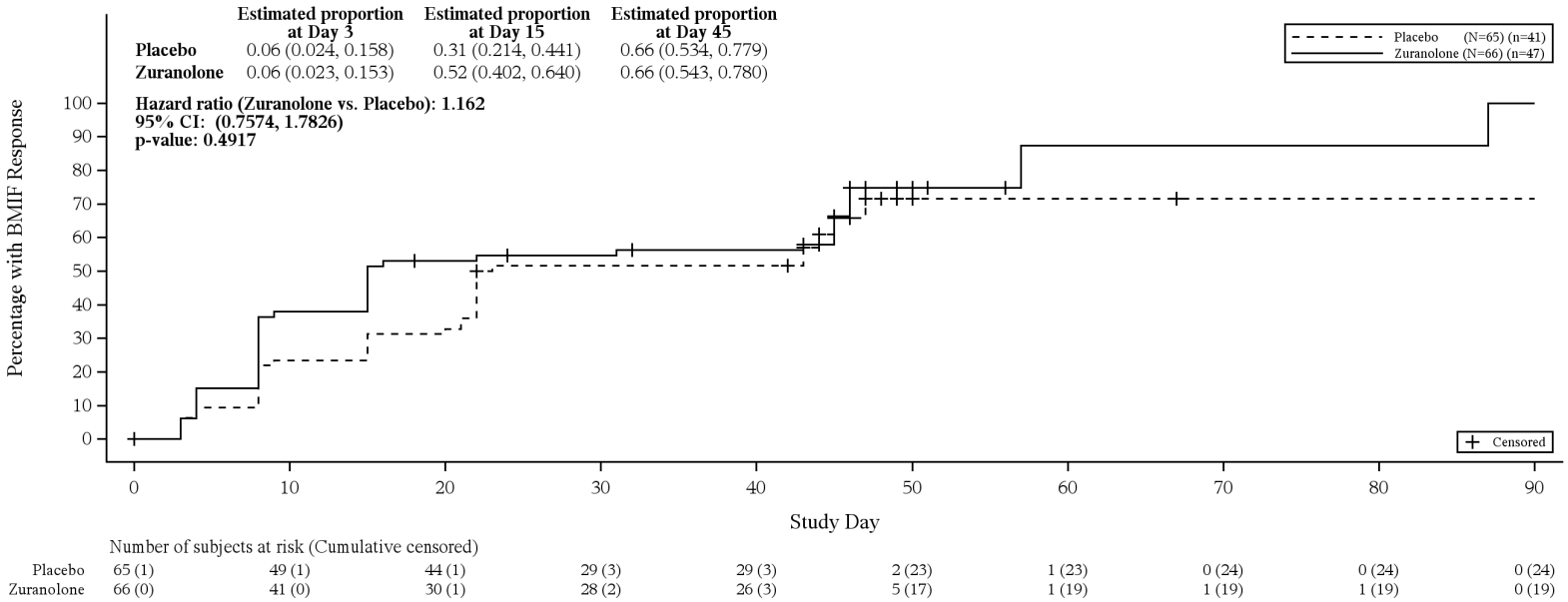
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Number of subjects at risk (Cumulative censored)

Placebo	65 (1)	49 (1)	44 (1)	29 (3)	29 (3)	2 (23)	1 (23)	0 (24)	0 (24)	0 (24)
Zuranolone	66 (0)	41 (0)	30 (1)	28 (2)	26 (3)	5 (17)	1 (19)	1 (19)	1 (19)	0 (19)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

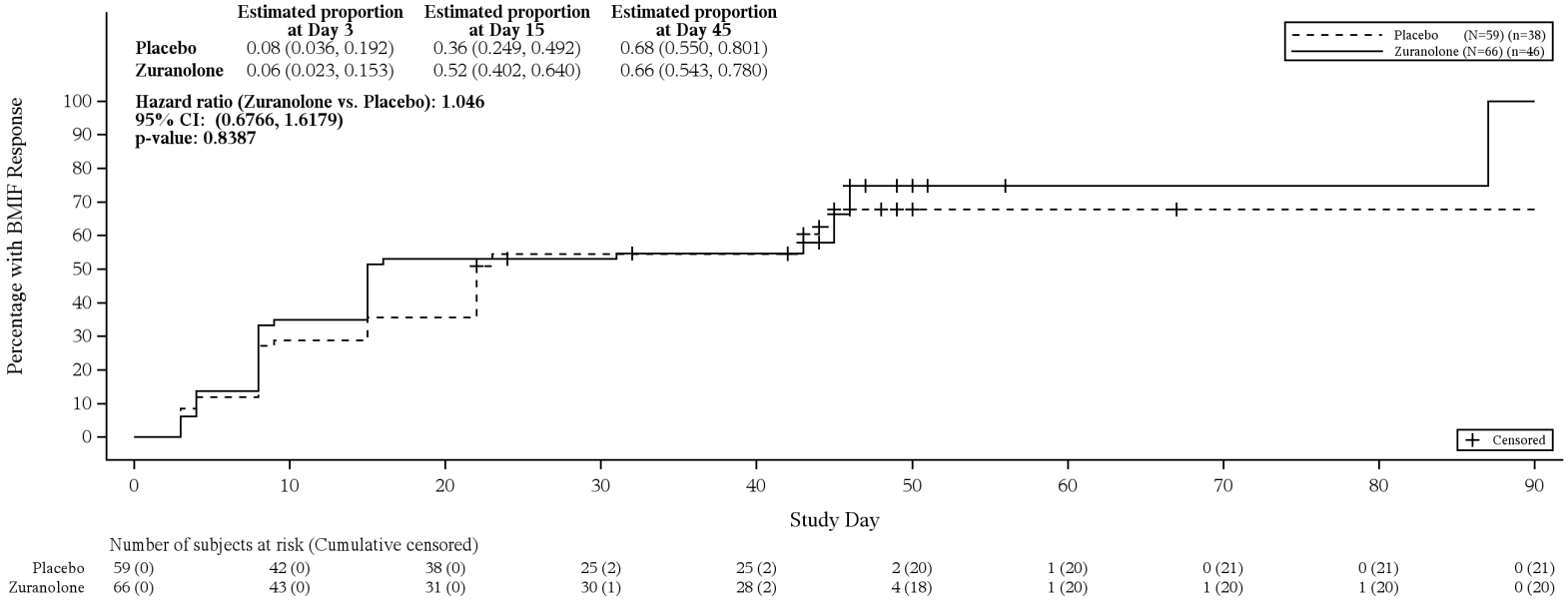
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Number of subjects at risk (Cumulative censored)

Placebo	59 (0)	42 (0)	38 (0)	25 (2)	25 (2)	2 (20)	1 (20)	0 (21)	0 (21)	0 (21)
Zuranolone	66 (0)	43 (0)	31 (0)	30 (1)	28 (2)	4 (18)	1 (20)	1 (20)	1 (20)	0 (20)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

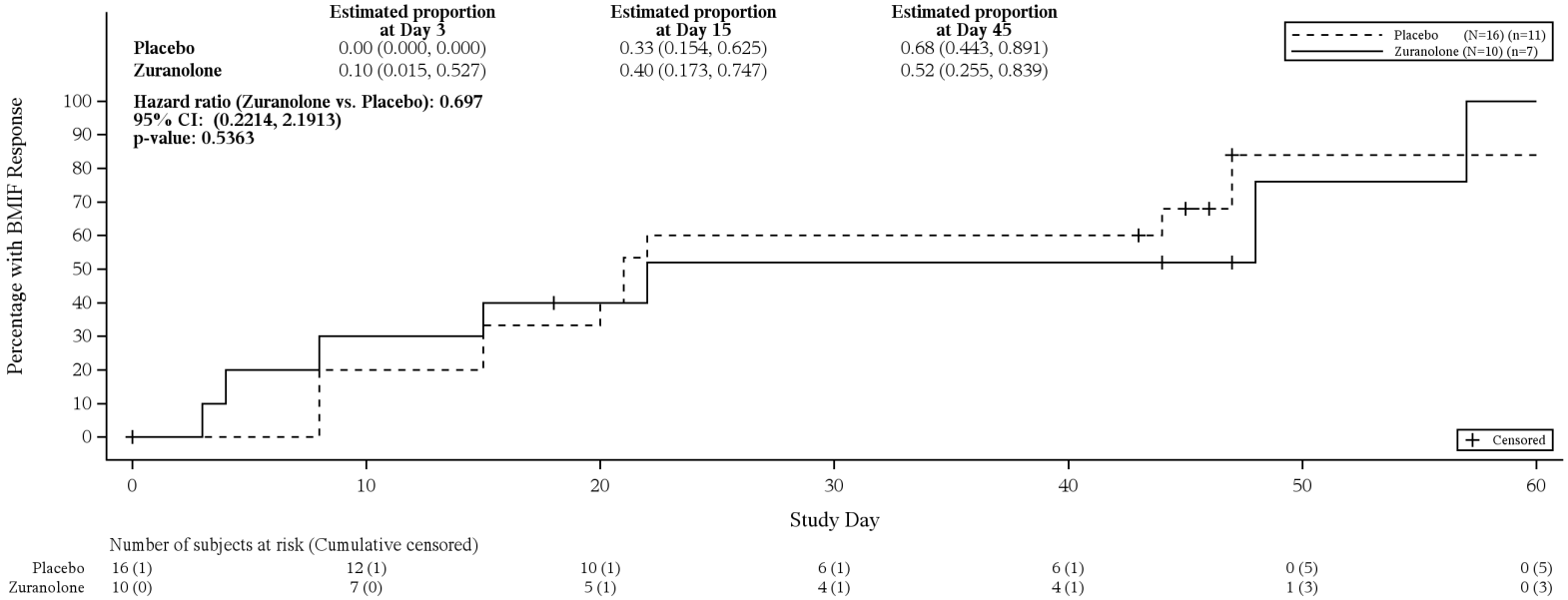
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 17 of 17

History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF total score response is defined as 18 points (15% of total scale range 0-120) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-resp15-tte-201-by.sas:f-bimf-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

3.1.3 Verschlechterung

3.1.3.1 Responder-Analysen

3.1.3.1 .1 ITT-Population

Summary of Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with worsening, n (%) [2]	2 (2.7)	0
Number of subjects with missing evaluation, n (%)	3 (4.0)	4 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.20
95% CI for the RR		(0.010, 4.044)
p-value for RR		0.2923
OR - Odds Ratio (Zuranolone vs. Placebo)		0.19
95% CI for the OR		(0.009, 4.070)
p-value for OR		0.2897
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.070, 0.018)
p-value for ARR		0.2388

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF total score worsening (18 points (15% of total scale range 0-120) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-201-ovr.sas:t-bimf-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with worsening, n (%) [2]	1 (1.3)	1 (1.3)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.99
95% CI for the RR		(0.063, 15.489)
p-value for RR		0.9925
OR - Odds Ratio (Zuranolone vs. Placebo)		0.99
95% CI for the OR		(0.061, 16.070)
p-value for OR		0.9925
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.037, 0.036)
p-value for ARR		0.9925

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF total score worsening (18 points (15% of total scale range 0-120) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-201-ovr.sas:t-bimf-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 3 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with worsening, n (%) [2]	1 (1.3)	1 (1.3)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.99
95% CI for the RR		(0.063, 15.489)
p-value for RR		0.9925
OR - Odds Ratio (Zuranolone vs. Placebo)		0.99
95% CI for the OR		(0.061, 16.070)
p-value for OR		0.9925
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.037, 0.036)
p-value for ARR		0.9925

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF total score worsening (18 points (15% of total scale range 0-120) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-201-ovr.sas:t-bimf-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with worsening, n (%) [2]	1 (1.3)	2 (2.6)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.97
95% CI for the RR		(0.183, 21.308)
p-value for RR		0.5754
OR - Odds Ratio (Zuranolone vs. Placebo)		2.00
95% CI for the OR		(0.177, 22.536)
p-value for OR		0.5749
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.031, 0.057)
p-value for ARR		0.5663

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF total score worsening (18 points (15% of total scale range 0-120) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-201-ovr.sas:t-bimf-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 5 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	0	1 (1.3)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		2.96
95% CI for the RR		(0.123, 71.552)
p-value for RR		0.5041
OR - Odds Ratio (Zuranolone vs. Placebo)		3.00
95% CI for the OR		(0.120, 74.819)
p-value for OR		0.5032
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.023, 0.049)
p-value for ARR		0.4803

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF total score worsening (18 points (15% of total scale range 0-120) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-201-ovr.sas:t-bimf-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.1.3.1 .2 Subgruppen

3.1.3.1 .2 .1 Interaktionstest

Summary of Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	1 (1.3)	1 (1.3)	
Number of subjects with response at Day 45, n (%)	0	1 (1.3)	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	0/25	0/17	
25 - 45, n / N (%)	1/50 (2.0)	1/59 (1.7)	
Day 45			
18 - 24, n / N (%)	0/25	0/17	
25 - 45, n / N (%)	0/50	1/59 (1.7)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score worsening is defined as 18 points (15% of total scale range 0-120) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-201-int.sas:t-bimf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	0/22	0/30	
>=28, n / N (%)	1/53 (1.9)	1/46 (2.2)	
Day 45			
<28, n / N (%)	0/22	0/30	
>=28, n / N (%)	0/53	1/46 (2.2)	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	1/32 (3.1)	0/31	
White, n / N (%)	0/40	1/44 (2.3)	
Day 45			
Black or African American, n / N (%)	0/32	1/31 (3.2)	
White, n / N (%)	0/40	0/44	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score worsening is defined as 18 points (15% of total scale range 0-120) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-201-int.sas:t-bimf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	1/62 (1.6)	1/60 (1.7)	
Day 45			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	0/62	1/60 (1.7)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score worsening is defined as 18 points (15% of total scale range 0-120) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-201-int.sas:t-bimf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	0/21	0/13	
25-29.9, n / N (%)	0/20	1/21 (4.8)	
>=30, n / N (%)	1/34 (2.9)	0/42	
Day 45			
<=24.9, n / N (%)	0/21	0/13	
25-29.9, n / N (%)	0/20	0/21	
>=30, n / N (%)	0/34	1/42 (2.4)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score worsening is defined as 18 points (15% of total scale range 0-120) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-201-int.sas:t-bimf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	0/32	1/32 (3.1)	
Postpartum, n / N (%)	1/43 (2.3)	0/44	
Day 45			
3rd Trimester, n / N (%)	0/32	1/32 (3.1)	
Postpartum, n / N (%)	0/43	0/44	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	1/65 (1.5)	1/66 (1.5)	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	0/65	1/66 (1.5)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score worsening is defined as 18 points (15% of total scale range 0-120) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-201-int.sas:t-bimf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	0/59	1/66 (1.5)	
Recurrent Episode, n / N (%)	1/16 (6.3)	0/10	
Day 45			
1st Episode, n / N (%)	0/59	1/66 (1.5)	
Recurrent Episode, n / N (%)	0/16	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	1/67 (1.5)	1/66 (1.5)	
Day 45			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	0/67	1/66 (1.5)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score worsening is defined as 18 points (15% of total scale range 0-120) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-201-int.sas:t-bimf-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

3.1.3.1 .2 .2 Subgruppenanalysen

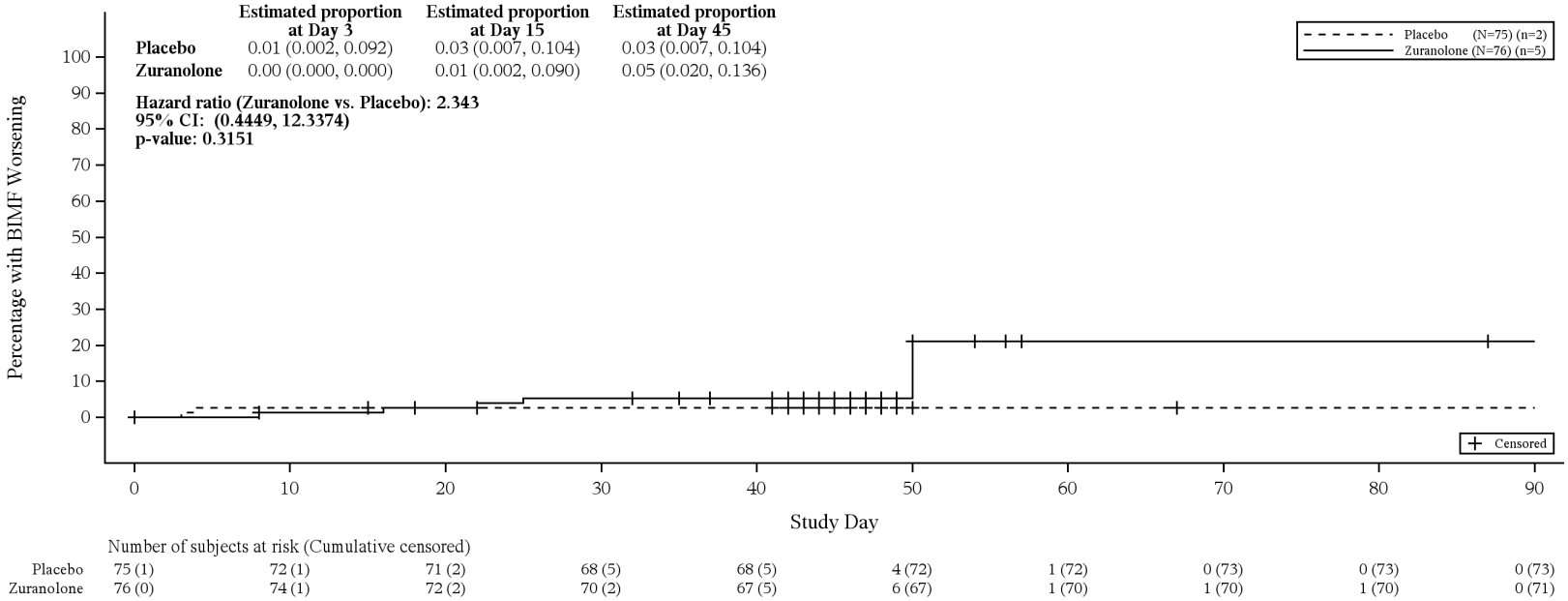
Nicht zutreffend.

3.1.3.2 TTE-Analysen

3.1.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing BIMF total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: BIMF total score worsening is defined as 18 points (15% of total scale range 0-120) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF total score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-bimf-wors15-tte-201-ovr.sas:f-bimf-wors15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	2 (2.7)	5 (6.6)
Time to first BIMF worsening (days) [3]		
25th percentile - Q1 (95% CI)	NE (NE, NE)	NE (50.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (50.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.343
95% CI for the HR		(0.4449 , 12.3374)
p-value for the HR		0.3151

NOTE 1: BIMF total score worsening is defined as 18 points (15% of total scale range 0-120) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing BIMF total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF total score worsening. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF total score, and treatment.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-tte-201-ovr.sas:t-bimf-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.1.3.2 .2 Subgruppen

3.1.3.2 .2 .1 Interaktionstest

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	2 (2.7)	5 (6.6)	
Age Group (years)			
18 - 24, n / N (%)	0/25	2/17 (11.8)	NA
25 - 45, n / N (%)	2/50 (4.0)	3/59 (5.1)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	0/22	2/30 (6.7)	NA
>=28, n / N (%)	2/53 (3.8)	3/46 (6.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	1/32 (3.1)	2/31 (6.5)	NA
White, n / N (%)	1/40 (2.5)	3/44 (6.8)	
Antidepressant Use at Baseline			
Yes, n / N (%)	0/13	0/16	NA
No, n / N (%)	2/62 (3.2)	5/60 (8.3)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score worsening is defined as 18 points (15% of total scale range 0-120) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-tte-201-int.sas:t-bimf-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	1/21 (4.8)	0/13	NA(a)
25-29.9, n / N (%)	0/20	1/21 (4.8)	NA(b)
>=30, n / N (%)	1/34 (2.9)	4/42 (9.5)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	0/32	4/32 (12.5)	NA
Postpartum, n / N (%)	2/43 (4.7)	1/44 (2.3)	
Family History of PPD			
Yes, n / N (%)	0/10	1/10 (10.0)	NA
No/Unknown, n / N (%)	2/65 (3.1)	4/66 (6.1)	
History of PPD			
1st Episode, n / N (%)	1/59 (1.7)	5/66 (7.6)	NA
Recurrent Episode, n / N (%)	1/16 (6.3)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/8	0/10	NA
>=20, n / N (%)	2/67 (3.0)	5/66 (7.6)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF total score worsening is defined as 18 points (15% of total scale range 0-120) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-wors15-tte-201-int.sas:t-bimf-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

3.1.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

3.1.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

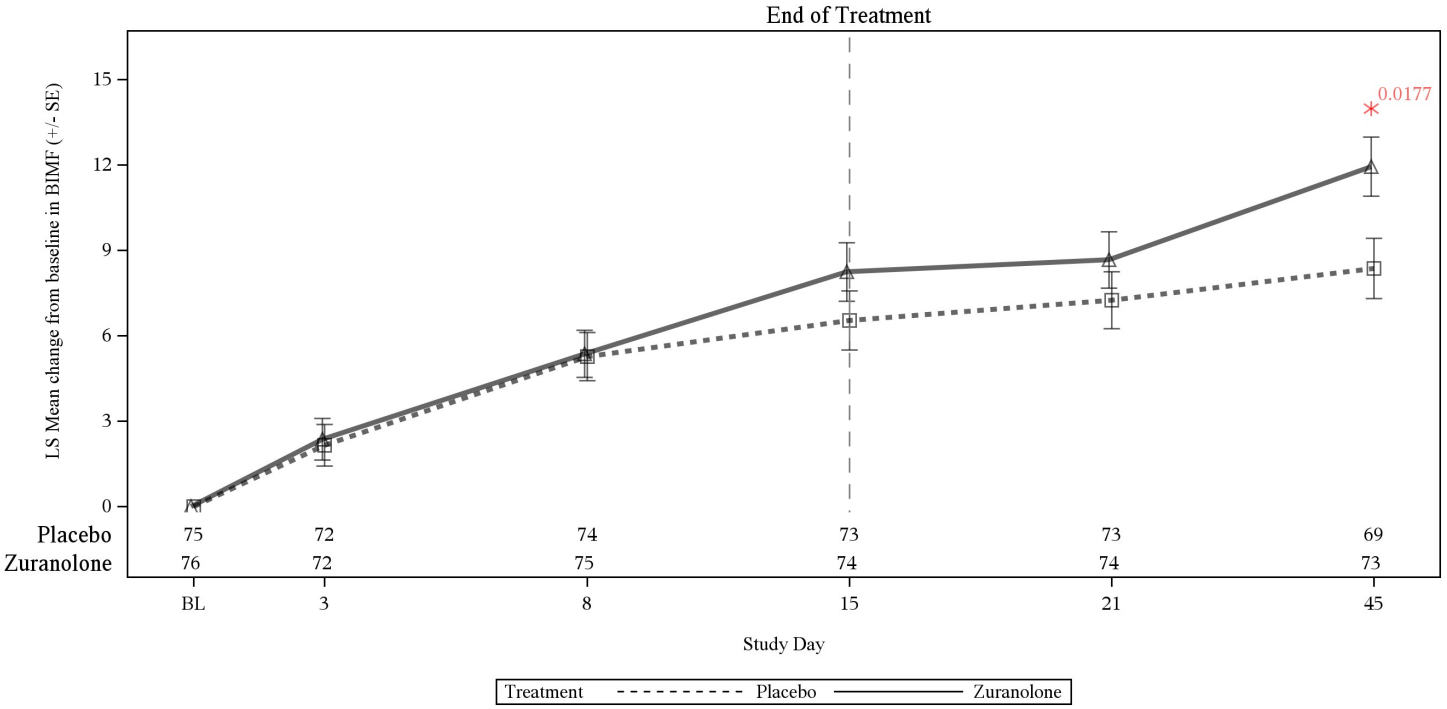
3.2 BIMF Kompetenz

3.2.1 MMRM

3.2.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/f-bimf-comp-mmrm-201-ovr.sas:f-bimf-comp-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score: 217-PPD-201B - ITT population

Page: 1 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 3		
n	72	72
LS Mean (SE)	2.16 (0.727)	2.37 (0.725)
95% CI for the LS Mean	0.72, 3.60	0.93, 3.80
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.21 (1.034)
95% CI for the LS Mean		-1.84, 2.25
p-value		0.8421
Hedges' g (Zuranolone vs. Placebo)		0.033
95% CI for Hedges' g		-0.2936, 0.3598
Day 8		
n	74	75
LS Mean (SE)	5.27 (0.839)	5.37 (0.832)
95% CI for the LS Mean	3.61, 6.93	3.72, 7.01
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.09 (1.188)
95% CI for the LS Mean		-2.26, 2.44
p-value		0.9385
Hedges' g (Zuranolone vs. Placebo)		0.013
95% CI for Hedges' g		-0.3085, 0.3337

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-ovr.sas:t-bimf-comp-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	6.54 (1.038)	8.25 (1.029)
95% CI for the LS Mean	4.48, 8.59	6.22, 10.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.72 (1.466)
95% CI for the LS Mean		-1.18, 4.62
p-value		0.2431
Hedges' g (Zuranolone vs. Placebo)		0.192
95% CI for Hedges' g		-0.1317, 0.5164
Day 21		
n	73	74
LS Mean (SE)	7.25 (0.999)	8.67 (0.990)
95% CI for the LS Mean	5.27, 9.22	6.71, 10.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.42 (1.412)
95% CI for the LS Mean		-1.37, 4.22
p-value		0.3148
Hedges' g (Zuranolone vs. Placebo)		0.166
95% CI for Hedges' g		-0.1583, 0.4894

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-ovr.sas:t-bimf-comp-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 45		
n	69	73
LS Mean (SE)	8.36 (1.060)	11.94 (1.041)
95% CI for the LS Mean	6.26, 10.46	9.88, 14.00
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.58 (1.491)
95% CI for the LS Mean		0.63, 6.53
p-value		0.0177
Hedges' g (Zuranolone vs. Placebo)		0.401
95% CI for Hedges' g		0.0689, 0.7337

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-ovr.sas:t-bimf-comp-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.2.1.2 Subgruppen

3.2.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.6961
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.8934
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.1433
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.7370
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup interaction analysis.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-int.sas:t-bimf-comp-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.8170(a)
25-29.9	20	21	0.8190(b)
>=30	34	42	0.5954(c)
Onset of PPD			
3rd Trimester	32	32	0.4844
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.1500
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.8504
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup interaction analysis.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-int.sas:t-bimf-comp-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

3.2.1.2 .2 Subgruppenanalysen

3.2.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Age Group: 217-PPD-201B - ITT population

Page: 1 of 6

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 3		
n	25	16
LS Mean (SE)	3.77 (1.225)	1.53 (1.537)
95% CI for the LS Mean	1.29, 6.25	-1.58, 4.64
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.24 (2.024)
95% CI for the LS Mean		-6.34, 1.86
p-value		0.2750
Hedges' g (Zuranolone vs. Placebo)		-0.348
95% CI for Hedges' g		-0.9797, 0.2843
Day 8		
n	25	17
LS Mean (SE)	6.29 (1.638)	5.17 (2.007)
95% CI for the LS Mean	2.97, 9.61	1.11, 9.24
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.12 (2.635)
95% CI for the LS Mean		-6.45, 4.22
p-value		0.6742
Hedges' g (Zuranolone vs. Placebo)		-0.131
95% CI for Hedges' g		-0.7474, 0.4861

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Age Group: 217-PPD-201B - ITT population

Page: 2 of 6

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	6.17 (1.718)	7.11 (2.103)
95% CI for the LS Mean	2.69, 9.65	2.86, 11.37
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.94 (2.758)
95% CI for the LS Mean		-4.64, 6.53
p-value		0.7338
Hedges' g (Zuranolone vs. Placebo)		0.106
95% CI for Hedges' g		-0.5109, 0.7222
Day 21		
n	25	16
LS Mean (SE)	7.01 (1.718)	8.20 (2.125)
95% CI for the LS Mean	3.52, 10.50	3.89, 12.51
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.19 (2.775)
95% CI for the LS Mean		-4.44, 6.82
p-value		0.6709
Hedges' g (Zuranolone vs. Placebo)		0.135
95% CI for Hedges' g		-0.4937, 0.7627

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Age Group: 217-PPD-201B - ITT population

Page: 3 of 6

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 45		
n	25	16
LS Mean (SE)	7.05 (1.813)	10.72 (2.251)
95% CI for the LS Mean	3.36, 10.74	6.14, 15.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.67 (2.931)
95% CI for the LS Mean		-2.29, 9.62
p-value		0.2194
Hedges' g (Zuranolone vs. Placebo)		0.393
95% CI for Hedges' g		-0.2405, 1.0260

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 3		
n	47	56
LS Mean (SE)	1.26 (0.870)	2.67 (0.797)
95% CI for the LS Mean	-0.47, 2.99	1.09, 4.25
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.41 (1.184)
95% CI for the LS Mean		-0.95, 3.76
p-value		0.2381
Hedges' g (Zuranolone vs. Placebo)		0.233
95% CI for Hedges' g		-0.1559, 0.6222
Day 8		
n	49	58
LS Mean (SE)	4.71 (0.993)	5.49 (0.910)
95% CI for the LS Mean	2.74, 6.68	3.68, 7.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.78 (1.351)
95% CI for the LS Mean		-1.90, 3.46
p-value		0.5656
Hedges' g (Zuranolone vs. Placebo)		0.111
95% CI for Hedges' g		-0.2695, 0.4916

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	6.69 (1.324)	8.66 (1.212)
95% CI for the LS Mean	4.06, 9.32	6.25, 11.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.97 (1.798)
95% CI for the LS Mean		-1.60, 5.54
p-value		0.2759
Hedges' g (Zuranolone vs. Placebo)		0.213
95% CI for Hedges' g		-0.1720, 0.5981
Day 21		
n	48	58
LS Mean (SE)	7.32 (1.265)	8.86 (1.155)
95% CI for the LS Mean	4.81, 9.83	6.57, 11.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.55 (1.716)
95% CI for the LS Mean		-1.86, 4.95
p-value		0.3695
Hedges' g (Zuranolone vs. Placebo)		0.175
95% CI for Hedges' g		-0.2085, 0.5578

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 45		
n	44	57
LS Mean (SE)	9.18 (1.371)	12.30 (1.232)
95% CI for the LS Mean	6.46, 11.90	9.85, 14.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.12 (1.846)
95% CI for the LS Mean		-0.55, 6.79
p-value		0.0942
Hedges' g (Zuranolone vs. Placebo)		0.337
95% CI for Hedges' g		-0.0591, 0.7330

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

3.2.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 3		
n	20	26
LS Mean (SE)	3.74 (1.162)	1.00 (0.991)
95% CI for the LS Mean	1.40, 6.08	-1.00, 2.99
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.74 (1.617)
95% CI for the LS Mean		-5.99, 0.51
p-value		0.0962
Hedges' g (Zuranolone vs. Placebo)		-0.496
95% CI for Hedges' g		-1.0878, 0.0956
Day 8		
n	22	29
LS Mean (SE)	4.73 (1.569)	4.48 (1.360)
95% CI for the LS Mean	1.58, 7.88	1.74, 7.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.25 (2.131)
95% CI for the LS Mean		-4.53, 4.02
p-value		0.9059
Hedges' g (Zuranolone vs. Placebo)		-0.033
95% CI for Hedges' g		-0.5873, 0.5211

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	6.23 (1.889)	8.75 (1.641)
95% CI for the LS Mean	2.43, 10.03	5.45, 12.05
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.52 (2.548)
95% CI for the LS Mean		-2.60, 7.64
p-value		0.3267
Hedges' g (Zuranolone vs. Placebo)		0.278
95% CI for Hedges' g		-0.2833, 0.8388
Day 21		
n	22	28
LS Mean (SE)	8.05 (1.996)	7.84 (1.738)
95% CI for the LS Mean	4.03, 12.07	4.35, 11.34
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.20 (2.690)
95% CI for the LS Mean		-5.62, 5.21
p-value		0.9404
Hedges' g (Zuranolone vs. Placebo)		-0.021
95% CI for Hedges' g		-0.5795, 0.5373

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 3 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 45		
n	22	28
LS Mean (SE)	7.55 (1.970)	14.17 (1.722)
95% CI for the LS Mean	3.57, 11.53	10.70, 17.65
Difference (Zuranolone - Placebo)		
LS Mean (SE)		6.62 (2.660)
95% CI for the LS Mean		1.26, 11.99
p-value		0.0167
Hedges' g (Zuranolone vs. Placebo)		0.698
95% CI for Hedges' g		0.1233, 1.2731

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 3		
n	52	46
LS Mean (SE)	1.56 (0.907)	3.07 (0.964)
95% CI for the LS Mean	-0.24, 3.36	1.16, 4.99
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.51 (1.325)
95% CI for the LS Mean		-1.12, 4.14
p-value		0.2565
Hedges' g (Zuranolone vs. Placebo)		0.229
95% CI for Hedges' g		-0.1687, 0.6274
Day 8		
n	52	46
LS Mean (SE)	5.46 (1.003)	5.94 (1.067)
95% CI for the LS Mean	3.47, 7.46	3.82, 8.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.48 (1.466)
95% CI for the LS Mean		-2.43, 3.39
p-value		0.7448
Hedges' g (Zuranolone vs. Placebo)		0.066
95% CI for Hedges' g		-0.3313, 0.4624

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	6.64 (1.270)	7.99 (1.347)
95% CI for the LS Mean	4.12, 9.16	5.31, 10.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.34 (1.852)
95% CI for the LS Mean		-2.33, 5.02
p-value		0.4698
Hedges' g (Zuranolone vs. Placebo)		0.146
95% CI for Hedges' g		-0.2527, 0.5455
Day 21		
n	51	46
LS Mean (SE)	6.86 (1.166)	9.18 (1.236)
95% CI for the LS Mean	4.54, 9.17	6.72, 11.64
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.33 (1.700)
95% CI for the LS Mean		-1.05, 5.70
p-value		0.1748
Hedges' g (Zuranolone vs. Placebo)		0.276
95% CI for Hedges' g		-0.1244, 0.6764

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 45		
n	47	45
LS Mean (SE)	8.65 (1.267)	10.57 (1.320)
95% CI for the LS Mean	6.13, 11.17	7.95, 13.20
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.92 (1.830)
95% CI for the LS Mean		-1.72, 5.57
p-value		0.2960
Hedges' g (Zuranolone vs. Placebo)		0.218
95% CI for Hedges' g		-0.1925, 0.6275

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

3.2.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Race Group: 217-PPD-201B - ITT population

Page: 1 of 6

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 3		
n	31	29
LS Mean (SE)	1.71 (1.091)	1.65 (1.110)
95% CI for the LS Mean	-0.48, 3.90	-0.58, 3.87
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.06 (1.559)
95% CI for the LS Mean		-3.19, 3.06
p-value		0.9685
Hedges' g (Zuranolone vs. Placebo)		-0.010
95% CI for Hedges' g		-0.5165, 0.4962
Day 8		
n	31	31
LS Mean (SE)	4.16 (1.245)	2.72 (1.247)
95% CI for the LS Mean	1.67, 6.65	0.23, 5.22
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.44 (1.765)
95% CI for the LS Mean		-4.97, 2.09
p-value		0.4185
Hedges' g (Zuranolone vs. Placebo)		-0.204
95% CI for Hedges' g		-0.7035, 0.2948

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	4.93 (1.317)	4.85 (1.318)
95% CI for the LS Mean	2.30, 7.57	2.21, 7.49
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.08 (1.866)
95% CI for the LS Mean		-3.82, 3.65
p-value		0.9646
Hedges' g (Zuranolone vs. Placebo)		-0.011
95% CI for Hedges' g		-0.5090, 0.4866
Day 21		
n	31	30
LS Mean (SE)	5.42 (1.338)	4.46 (1.347)
95% CI for the LS Mean	2.74, 8.10	1.76, 7.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.96 (1.901)
95% CI for the LS Mean		-4.77, 2.85
p-value		0.6159
Hedges' g (Zuranolone vs. Placebo)		-0.128
95% CI for Hedges' g		-0.6300, 0.3749

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 45		
n	30	30
LS Mean (SE)	7.81 (1.623)	8.59 (1.624)
95% CI for the LS Mean	4.54, 11.07	5.32, 11.85
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.78 (2.298)
95% CI for the LS Mean		-3.84, 5.40
p-value		0.7355
Hedges' g (Zuranolone vs. Placebo)		0.087
95% CI for Hedges' g		-0.4197, 0.5929

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 3		
n	39	42
LS Mean (SE)	2.93 (1.021)	2.67 (0.980)
95% CI for the LS Mean	0.89, 4.96	0.71, 4.62
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.26 (1.434)
95% CI for the LS Mean		-3.12, 2.60
p-value		0.8546
Hedges' g (Zuranolone vs. Placebo)		-0.040
95% CI for Hedges' g		-0.4764, 0.3954
Day 8		
n	40	43
LS Mean (SE)	6.65 (1.159)	7.18 (1.113)
95% CI for the LS Mean	4.34, 8.96	4.97, 9.40
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.53 (1.623)
95% CI for the LS Mean		-2.70, 3.76
p-value		0.7437
Hedges' g (Zuranolone vs. Placebo)		0.071
95% CI for Hedges' g		-0.3593, 0.5021

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	7.75 (1.568)	10.63 (1.504)
95% CI for the LS Mean	4.63, 10.87	7.64, 13.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.88 (2.185)
95% CI for the LS Mean		-1.47, 7.23
p-value		0.1912
Hedges' g (Zuranolone vs. Placebo)		0.290
95% CI for Hedges' g		-0.1477, 0.7285
Day 21		
n	39	43
LS Mean (SE)	8.45 (1.376)	11.94 (1.316)
95% CI for the LS Mean	5.70, 11.19	9.31, 14.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.49 (1.918)
95% CI for the LS Mean		-0.34, 7.32
p-value		0.0731
Hedges' g (Zuranolone vs. Placebo)		0.399
95% CI for Hedges' g		-0.0390, 0.8364

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 45		
n	36	42
LS Mean (SE)	8.64 (1.466)	14.38 (1.388)
95% CI for the LS Mean	5.72, 11.56	11.61, 17.15
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.74 (2.032)
95% CI for the LS Mean		1.69, 9.79
p-value		0.0061
Hedges' g (Zuranolone vs. Placebo)		0.635
95% CI for Hedges' g		0.1790, 1.0913

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

3.2.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 3		
n	13	14
LS Mean (SE)	2.96 (1.696)	1.85 (1.643)
95% CI for the LS Mean	-0.56, 6.48	-1.55, 5.26
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.10 (2.372)
95% CI for the LS Mean		-6.02, 3.82
p-value		0.6464
Hedges' g (Zuranolone vs. Placebo)		-0.174
95% CI for Hedges' g		-0.9300, 0.5826
Day 8		
n	13	16
LS Mean (SE)	7.11 (1.948)	7.16 (1.758)
95% CI for the LS Mean	3.10, 11.12	3.55, 10.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.05 (2.634)
95% CI for the LS Mean		-5.36, 5.47
p-value		0.9845
Hedges' g (Zuranolone vs. Placebo)		0.007
95% CI for Hedges' g		-0.7247, 0.7390

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	8.57 (2.521)	12.18 (2.318)
95% CI for the LS Mean	3.38, 13.77	7.41, 16.95
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.61 (3.432)
95% CI for the LS Mean		-3.46, 10.67
p-value		0.3031
Hedges' g (Zuranolone vs. Placebo)		0.387
95% CI for Hedges' g		-0.3628, 1.1364
Day 21		
n	12	15
LS Mean (SE)	8.38 (2.282)	11.80 (2.069)
95% CI for the LS Mean	3.67, 13.08	7.53, 16.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.42 (3.087)
95% CI for the LS Mean		-2.94, 9.78
p-value		0.2783
Hedges' g (Zuranolone vs. Placebo)		0.416
95% CI for Hedges' g		-0.3508, 1.1835

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 45		
n	11	15
LS Mean (SE)	9.12 (2.811)	14.15 (2.536)
95% CI for the LS Mean	3.25, 14.99	8.84, 19.46
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.02 (3.793)
95% CI for the LS Mean		-2.90, 12.95
p-value		0.2007
Hedges' g (Zuranolone vs. Placebo)		0.509
95% CI for Hedges' g		-0.2810, 1.2995

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 3		
n	59	58
LS Mean (SE)	1.96 (0.798)	2.50 (0.807)
95% CI for the LS Mean	0.38, 3.54	0.90, 4.10
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.54 (1.143)
95% CI for the LS Mean		-1.73, 2.80
p-value		0.6382
Hedges' g (Zuranolone vs. Placebo)		0.087
95% CI for Hedges' g		-0.2760, 0.4492
Day 8		
n	61	59
LS Mean (SE)	4.86 (0.935)	4.92 (0.948)
95% CI for the LS Mean	3.01, 6.71	3.04, 6.80
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.06 (1.338)
95% CI for the LS Mean		-2.59, 2.71
p-value		0.9626
Hedges' g (Zuranolone vs. Placebo)		0.009
95% CI for Hedges' g		-0.3494, 0.3664

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	6.07 (1.137)	7.28 (1.148)
95% CI for the LS Mean	3.82, 8.33	5.01, 9.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.21 (1.622)
95% CI for the LS Mean		-2.00, 4.42
p-value		0.4574
Hedges' g (Zuranolone vs. Placebo)		0.136
95% CI for Hedges' g		-0.2239, 0.4956
Day 21		
n	61	59
LS Mean (SE)	6.97 (1.116)	7.90 (1.129)
95% CI for the LS Mean	4.76, 9.18	5.66, 10.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.93 (1.593)
95% CI for the LS Mean		-2.23, 4.09
p-value		0.5607
Hedges' g (Zuranolone vs. Placebo)		0.106
95% CI for Hedges' g		-0.2523, 0.4640

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 45		
n	58	58
LS Mean (SE)	8.29 (1.165)	11.42 (1.172)
95% CI for the LS Mean	5.98, 10.60	9.10, 13.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.14 (1.658)
95% CI for the LS Mean		-0.15, 6.42
p-value		0.0612
Hedges' g (Zuranolone vs. Placebo)		0.349
95% CI for Hedges' g		-0.0176, 0.7158

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

3.2.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 3		
n	20	13
LS Mean (SE)	2.77 (1.087)	-0.49 (1.359)
95% CI for the LS Mean	0.54, 5.00	-3.28, 2.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.26 (1.769)
95% CI for the LS Mean		-6.89, 0.36
p-value		0.0757
Hedges' g (Zuranolone vs. Placebo)		-0.641
95% CI for Hedges' g		-1.3565, 0.0739
Day 8		
n	20	13
LS Mean (SE)	5.22 (1.575)	4.97 (1.961)
95% CI for the LS Mean	2.01, 8.43	0.97, 8.97
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.25 (2.535)
95% CI for the LS Mean		-5.42, 4.91
p-value		0.9215
Hedges' g (Zuranolone vs. Placebo)		-0.035
95% CI for Hedges' g		-0.7328, 0.6638

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	5.82 (1.941)	6.97 (2.413)
95% CI for the LS Mean	1.86, 9.78	2.04, 11.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.15 (3.113)
95% CI for the LS Mean		-5.21, 7.50
p-value		0.7148
Hedges' g (Zuranolone vs. Placebo)		0.128
95% CI for Hedges' g		-0.5707, 0.8272
Day 21		
n	19	12
LS Mean (SE)	6.71 (1.876)	9.87 (2.351)
95% CI for the LS Mean	2.85, 10.57	5.04, 14.70
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.16 (3.022)
95% CI for the LS Mean		-3.05, 9.37
p-value		0.3054
Hedges' g (Zuranolone vs. Placebo)		0.375
95% CI for Hedges' g		-0.3533, 1.1041

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 45		
n	18	12
LS Mean (SE)	6.67 (2.412)	13.78 (2.980)
95% CI for the LS Mean	1.73, 11.61	7.68, 19.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		7.11 (3.845)
95% CI for the LS Mean		-0.76, 14.98
p-value		0.0748
Hedges' g (Zuranolone vs. Placebo)		0.670
95% CI for Hedges' g		-0.0795, 1.4202

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 3		
n	19	20
LS Mean (SE)	3.62 (1.558)	5.08 (1.540)
95% CI for the LS Mean	0.45, 6.79	1.95, 8.22
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.46 (2.193)
95% CI for the LS Mean		-3.00, 5.93
p-value		0.5088
Hedges' g (Zuranolone vs. Placebo)		0.210
95% CI for Hedges' g		-0.4200, 0.8392
Day 8		
n	20	20
LS Mean (SE)	5.89 (1.782)	7.71 (1.762)
95% CI for the LS Mean	2.29, 9.50	4.15, 11.28
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.82 (2.508)
95% CI for the LS Mean		-3.26, 6.90
p-value		0.4726
Hedges' g (Zuranolone vs. Placebo)		0.225
95% CI for Hedges' g		-0.3969, 0.8466

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	8.79 (2.060)	11.24 (2.022)
95% CI for the LS Mean	4.60, 12.98	7.13, 15.35
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.44 (2.888)
95% CI for the LS Mean		-3.43, 8.32
p-value		0.4035
Hedges' g (Zuranolone vs. Placebo)		0.262
95% CI for Hedges' g		-0.3602, 0.8847
Day 21		
n	20	21
LS Mean (SE)	8.84 (2.031)	11.99 (1.981)
95% CI for the LS Mean	4.72, 12.97	7.96, 16.01
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.14 (2.838)
95% CI for the LS Mean		-2.63, 8.91
p-value		0.2759
Hedges' g (Zuranolone vs. Placebo)		0.339
95% CI for Hedges' g		-0.2774, 0.9561

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	**Zuranolone (N=21)**
Day 45		
n	20	20
LS Mean (SE)	10.19 (1.960)	14.23 (1.926)
95% CI for the LS Mean	6.19, 14.20	10.30, 18.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.03 (2.749)
95% CI for the LS Mean		-1.58, 9.65
p-value		0.1527
Hedges' g (Zuranolone vs. Placebo)		0.455
95% CI for Hedges' g		-0.1730, 1.0825

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 3		
n	33	39
LS Mean (SE)	0.44 (1.031)	2.25 (0.943)
95% CI for the LS Mean	-1.62, 2.50	0.36, 4.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.81 (1.418)
95% CI for the LS Mean		-1.03, 4.64
p-value		0.2072
Hedges' g (Zuranolone vs. Placebo)		0.298
95% CI for Hedges' g		-0.1679, 0.7643
Day 8		
n	34	42
LS Mean (SE)	4.54 (1.192)	4.73 (1.076)
95% CI for the LS Mean	2.17, 6.92	2.58, 6.87
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.18 (1.623)
95% CI for the LS Mean		-3.05, 3.42
p-value		0.9105
Hedges' g (Zuranolone vs. Placebo)		0.026
95% CI for Hedges' g		-0.4264, 0.4779

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	5.21 (1.474)	7.51 (1.331)
95% CI for the LS Mean	2.27, 8.15	4.85, 10.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.29 (1.999)
95% CI for the LS Mean		-1.69, 6.28
p-value		0.2549
Hedges' g (Zuranolone vs. Placebo)		0.266
95% CI for Hedges' g		-0.1948, 0.7259
Day 21		
n	34	41
LS Mean (SE)	6.22 (1.390)	7.04 (1.261)
95% CI for the LS Mean	3.45, 8.99	4.53, 9.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.82 (1.891)
95% CI for the LS Mean		-2.95, 4.59
p-value		0.6654
Hedges' g (Zuranolone vs. Placebo)		0.100
95% CI for Hedges' g		-0.3552, 0.5546

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 45		
n	31	41
LS Mean (SE)	7.59 (1.425)	10.57 (1.257)
95% CI for the LS Mean	4.74, 10.44	8.06, 13.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.98 (1.916)
95% CI for the LS Mean		-0.85, 6.81
p-value		0.1245
Hedges' g (Zuranolone vs. Placebo)		0.366
95% CI for Hedges' g		-0.1038, 0.8368

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 3		
n	31	32
LS Mean (SE)	3.38 (1.078)	2.74 (1.060)
95% CI for the LS Mean	1.22, 5.54	0.61, 4.86
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.64 (1.515)
95% CI for the LS Mean		-3.67, 2.39
p-value		0.6738
Hedges' g (Zuranolone vs. Placebo)		-0.105
95% CI for Hedges' g		-0.5996, 0.3890
Day 8		
n	31	32
LS Mean (SE)	5.73 (1.353)	4.17 (1.332)
95% CI for the LS Mean	3.02, 8.44	1.51, 6.84
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.56 (1.901)
95% CI for the LS Mean		-5.36, 2.25
p-value		0.4157
Hedges' g (Zuranolone vs. Placebo)		-0.204
95% CI for Hedges' g		-0.6992, 0.2912

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	4.99 (1.532)	7.36 (1.508)
95% CI for the LS Mean	1.92, 8.06	4.34, 10.38
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.37 (2.152)
95% CI for the LS Mean		-1.93, 6.68
p-value		0.2749
Hedges' g (Zuranolone vs. Placebo)		0.274
95% CI for Hedges' g		-0.2219, 0.7705
Day 21		
n	30	31
LS Mean (SE)	7.37 (1.534)	7.35 (1.509)
95% CI for the LS Mean	4.29, 10.44	4.32, 10.37
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.02 (2.153)
95% CI for the LS Mean		-4.34, 4.29
p-value		0.9918
Hedges' g (Zuranolone vs. Placebo)		-0.003
95% CI for Hedges' g		-0.5046, 0.4993

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 45		
n	29	30
LS Mean (SE)	7.98 (1.598)	10.25 (1.571)
95% CI for the LS Mean	4.78, 11.18	7.10, 13.40
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.27 (2.242)
95% CI for the LS Mean		-2.22, 6.77
p-value		0.3150
Hedges' g (Zuranolone vs. Placebo)		0.261
95% CI for Hedges' g		-0.2520, 0.7731

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 3		
n	41	40
LS Mean (SE)	1.21 (0.988)	2.03 (0.996)
95% CI for the LS Mean	-0.76, 3.18	0.04, 4.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.82 (1.425)
95% CI for the LS Mean		-2.02, 3.66
p-value		0.5652
Hedges' g (Zuranolone vs. Placebo)		0.127
95% CI for Hedges' g		-0.3089, 0.5632
Day 8		
n	43	43
LS Mean (SE)	4.92 (1.083)	6.28 (1.082)
95% CI for the LS Mean	2.76, 7.07	4.13, 8.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.36 (1.550)
95% CI for the LS Mean		-1.72, 4.44
p-value		0.3831
Hedges' g (Zuranolone vs. Placebo)		0.187
95% CI for Hedges' g		-0.2362, 0.6110

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	7.69 (1.430)	8.95 (1.425)
95% CI for the LS Mean	4.84, 10.53	6.11, 11.79
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.26 (2.034)
95% CI for the LS Mean		-2.78, 5.31
p-value		0.5365
Hedges' g (Zuranolone vs. Placebo)		0.134
95% CI for Hedges' g		-0.2939, 0.5624
Day 21		
n	43	43
LS Mean (SE)	7.17 (1.334)	9.69 (1.331)
95% CI for the LS Mean	4.52, 9.83	7.04, 12.34
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.51 (1.900)
95% CI for the LS Mean		-1.27, 6.29
p-value		0.1896
Hedges' g (Zuranolone vs. Placebo)		0.283
95% CI for Hedges' g		-0.1420, 0.7076

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 45		
n	40	43
LS Mean (SE)	8.66 (1.436)	13.16 (1.413)
95% CI for the LS Mean	5.80, 11.52	10.34, 15.98
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.50 (2.029)
95% CI for the LS Mean		0.45, 8.55
p-value		0.0298
Hedges' g (Zuranolone vs. Placebo)		0.483
95% CI for Hedges' g		0.0458, 0.9193

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

3.2.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 3		
n	10	10
LS Mean (SE)	1.93 (1.701)	2.51 (1.705)
95% CI for the LS Mean	-1.67, 5.52	-1.09, 6.11
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.58 (2.502)
95% CI for the LS Mean		-4.69, 5.86
p-value		0.8184
Hedges' g (Zuranolone vs. Placebo)		0.100
95% CI for Hedges' g		-0.7772, 0.9769
Day 8		
n	10	10
LS Mean (SE)	6.23 (2.890)	4.31 (2.892)
95% CI for the LS Mean	0.03, 12.42	-1.89, 10.51
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.92 (4.144)
95% CI for the LS Mean		-10.78, 6.95
p-value		0.6506
Hedges' g (Zuranolone vs. Placebo)		-0.198
95% CI for Hedges' g		-1.0768, 0.6806

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	10.03 (3.803)	6.11 (3.805)
95% CI for the LS Mean	1.93, 18.12	-1.99, 14.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.92 (5.422)
95% CI for the LS Mean		-15.45, 7.61
p-value		0.4809
Hedges' g (Zuranolone vs. Placebo)		-0.309
95% CI for Hedges' g		-1.1911, 0.5724
Day 21		
n	10	10
LS Mean (SE)	10.03 (3.561)	7.31 (3.563)
95% CI for the LS Mean	2.41, 17.64	-0.31, 14.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.72 (5.083)
95% CI for the LS Mean		-13.57, 8.14
p-value		0.6010
Hedges' g (Zuranolone vs. Placebo)		-0.229
95% CI for Hedges' g		-1.1083, 0.6505

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 45		
n	9	10
LS Mean (SE)	12.45 (3.960)	9.11 (3.903)
95% CI for the LS Mean	3.27, 21.63	0.02, 18.19
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.34 (5.607)
95% CI for the LS Mean		-16.32, 9.64
p-value		0.5685
Hedges' g (Zuranolone vs. Placebo)		-0.261
95% CI for Hedges' g		-1.1656, 0.6431

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 3		
n	62	62
LS Mean (SE)	2.18 (0.798)	2.41 (0.794)
95% CI for the LS Mean	0.60, 3.76	0.84, 3.99
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.23 (1.139)
95% CI for the LS Mean		-2.02, 2.49
p-value		0.8375
Hedges' g (Zuranolone vs. Placebo)		0.037
95% CI for Hedges' g		-0.3154, 0.3887
Day 8		
n	64	65
LS Mean (SE)	5.11 (0.902)	5.55 (0.893)
95% CI for the LS Mean	3.33, 6.90	3.79, 7.32
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.44 (1.280)
95% CI for the LS Mean		-2.09, 2.97
p-value		0.7313
Hedges' g (Zuranolone vs. Placebo)		0.060
95% CI for Hedges' g		-0.2850, 0.4055

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	5.96 (1.087)	8.61 (1.076)
95% CI for the LS Mean	3.81, 8.11	6.48, 10.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.65 (1.539)
95% CI for the LS Mean		-0.40, 5.69
p-value		0.0876
Hedges' g (Zuranolone vs. Placebo)		0.304
95% CI for Hedges' g		-0.0461, 0.6536
Day 21		
n	63	64
LS Mean (SE)	6.81 (1.063)	8.90 (1.053)
95% CI for the LS Mean	4.70, 8.91	6.82, 10.99
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.10 (1.506)
95% CI for the LS Mean		-0.89, 5.08
p-value		0.1666
Hedges' g (Zuranolone vs. Placebo)		0.245
95% CI for Hedges' g		-0.1037, 0.5946

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 45		
n	60	63
LS Mean (SE)	7.95 (1.143)	12.41 (1.124)
95% CI for the LS Mean	5.68, 10.21	10.18, 14.64
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.46 (1.611)
95% CI for the LS Mean		1.27, 7.65
p-value		0.0066
Hedges' g (Zuranolone vs. Placebo)		0.496
95% CI for Hedges' g		0.1374, 0.8553

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

3.2.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 3		
n	58	62
LS Mean (SE)	2.59 (0.814)	2.49 (0.782)
95% CI for the LS Mean	0.98, 4.21	0.94, 4.04
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.11 (1.137)
95% CI for the LS Mean		-2.36, 2.15
p-value		0.9255
Hedges' g (Zuranolone vs. Placebo)		-0.017
95% CI for Hedges' g		-0.3750, 0.3410
Day 8		
n	59	65
LS Mean (SE)	5.97 (0.945)	5.40 (0.897)
95% CI for the LS Mean	4.09, 7.84	3.62, 7.17
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.57 (1.310)
95% CI for the LS Mean		-3.16, 2.02
p-value		0.6644
Hedges' g (Zuranolone vs. Placebo)		-0.078
95% CI for Hedges' g		-0.4303, 0.2749

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	6.81 (1.204)	8.55 (1.146)
95% CI for the LS Mean	4.43, 9.20	6.28, 10.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.74 (1.668)
95% CI for the LS Mean		-1.57, 5.04
p-value		0.2996
Hedges' g (Zuranolone vs. Placebo)		0.187
95% CI for Hedges' g		-0.1676, 0.5414
Day 21		
n	58	65
LS Mean (SE)	7.56 (1.162)	8.87 (1.100)
95% CI for the LS Mean	5.26, 9.86	6.69, 11.05
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.31 (1.606)
95% CI for the LS Mean		-1.87, 4.50
p-value		0.4147
Hedges' g (Zuranolone vs. Placebo)		0.147
95% CI for Hedges' g		-0.2075, 0.5015

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 45		
n	55	64
LS Mean (SE)	8.55 (1.263)	12.38 (1.186)
95% CI for the LS Mean	6.05, 11.05	10.03, 14.73
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.83 (1.738)
95% CI for the LS Mean		0.38, 7.27
p-value		0.0298
Hedges' g (Zuranolone vs. Placebo)		0.402
95% CI for Hedges' g		0.0385, 0.7664

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 3		
n	14	10
LS Mean (SE)	0.07 (1.687)	2.14 (2.043)
95% CI for the LS Mean	-3.42, 3.56	-2.08, 6.37
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.07 (2.697)
95% CI for the LS Mean		-3.50, 7.65
p-value		0.4494
Hedges' g (Zuranolone vs. Placebo)		0.308
95% CI for Hedges' g		-0.5086, 1.1237
Day 8		
n	15	10
LS Mean (SE)	2.30 (1.918)	5.74 (2.357)
95% CI for the LS Mean	-1.68, 6.28	0.85, 10.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.44 (3.078)
95% CI for the LS Mean		-2.94, 9.82
p-value		0.2754
Hedges' g (Zuranolone vs. Placebo)		0.442
95% CI for Hedges' g		-0.3679, 1.2510

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	5.19 (1.970)	6.94 (2.390)
95% CI for the LS Mean	1.08, 9.30	1.95, 11.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.76 (3.136)
95% CI for the LS Mean		-4.78, 8.29
p-value		0.5816
Hedges' g (Zuranolone vs. Placebo)		0.224
95% CI for Hedges' g		-0.5901, 1.0378
Day 21		
n	15	9
LS Mean (SE)	5.77 (1.894)	7.83 (2.380)
95% CI for the LS Mean	1.83, 9.71	2.90, 12.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.06 (3.083)
95% CI for the LS Mean		-4.32, 8.45
p-value		0.5100
Hedges' g (Zuranolone vs. Placebo)		0.273
95% CI for Hedges' g		-0.5574, 1.1026

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-comp-mmrm-201-by.sas:t-bimf-comp-mmrm-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 45		
n	14	9
LS Mean (SE)	7.36 (1.394)	9.50 (1.738)
95% CI for the LS Mean	4.42, 10.29	5.85, 13.15
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.14 (2.288)
95% CI for the LS Mean		-2.66, 6.95
p-value		0.3612
Hedges' g (Zuranolone vs. Placebo)		0.386
95% CI for Hedges' g		-0.4590, 1.2305

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

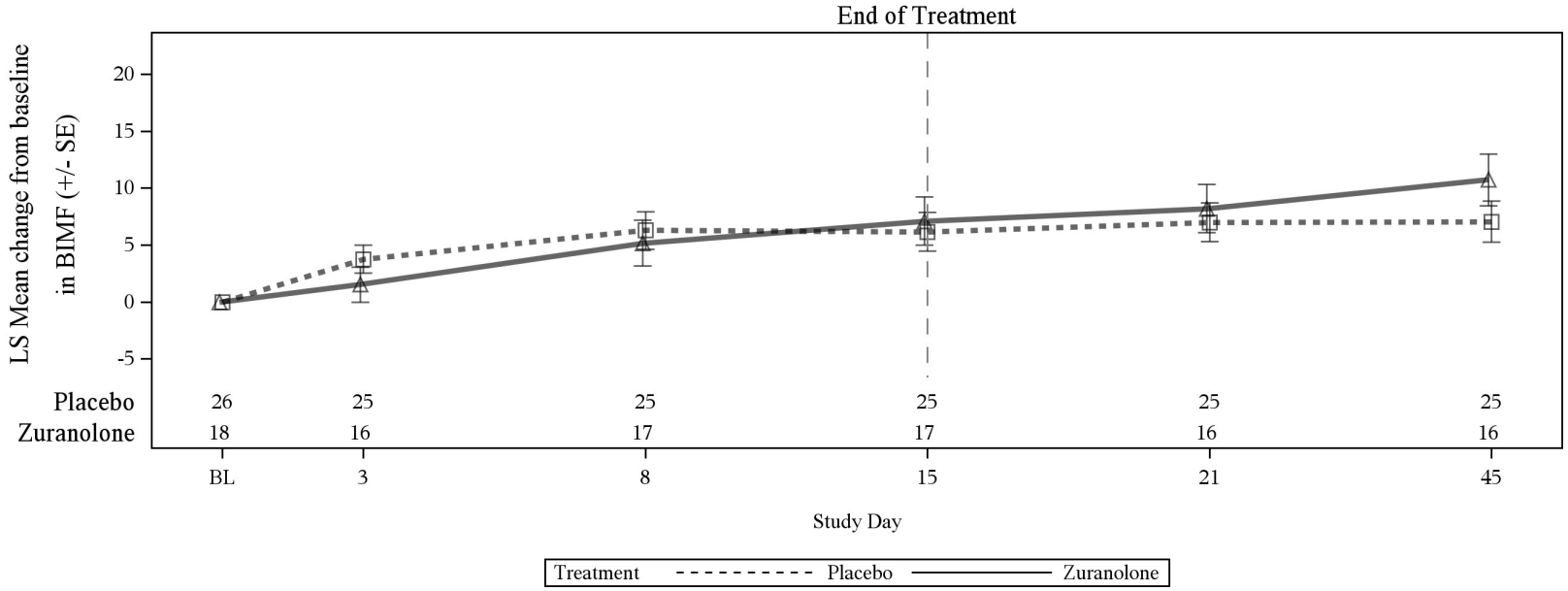
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3.2.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

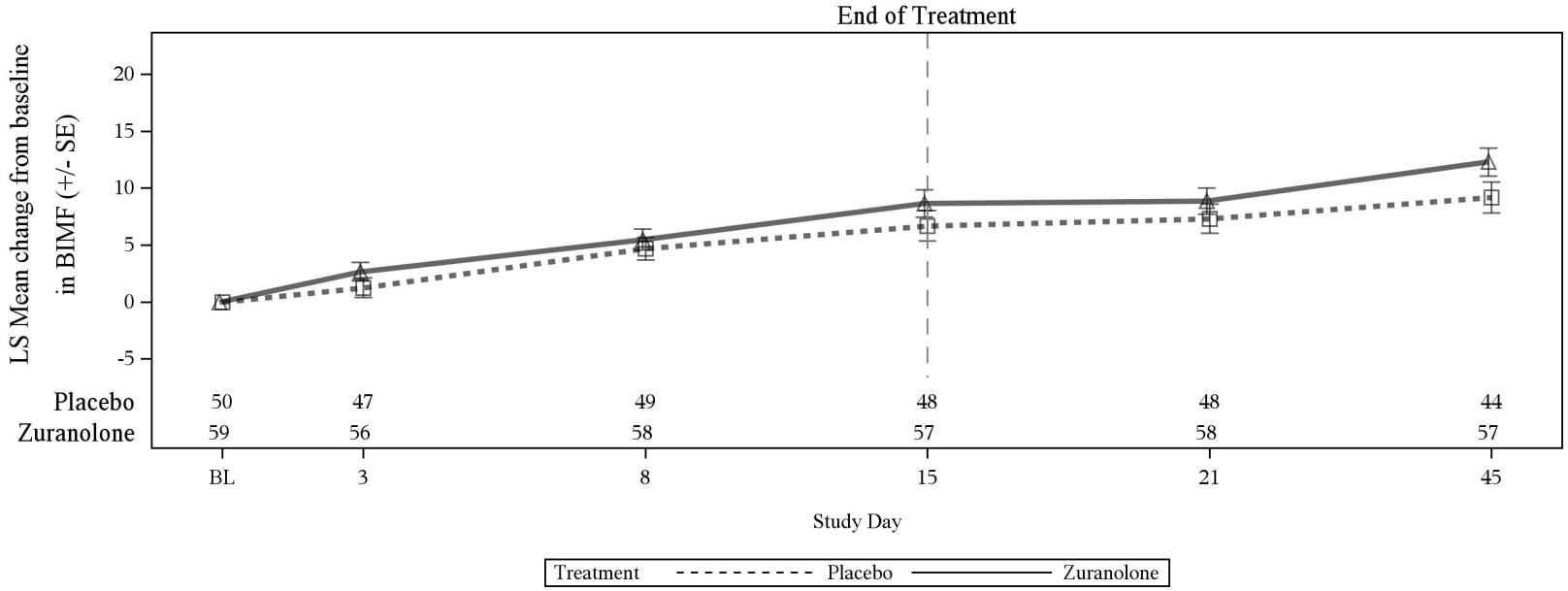
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-comp-mmrm-201-by.sas:f-bimf-comp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

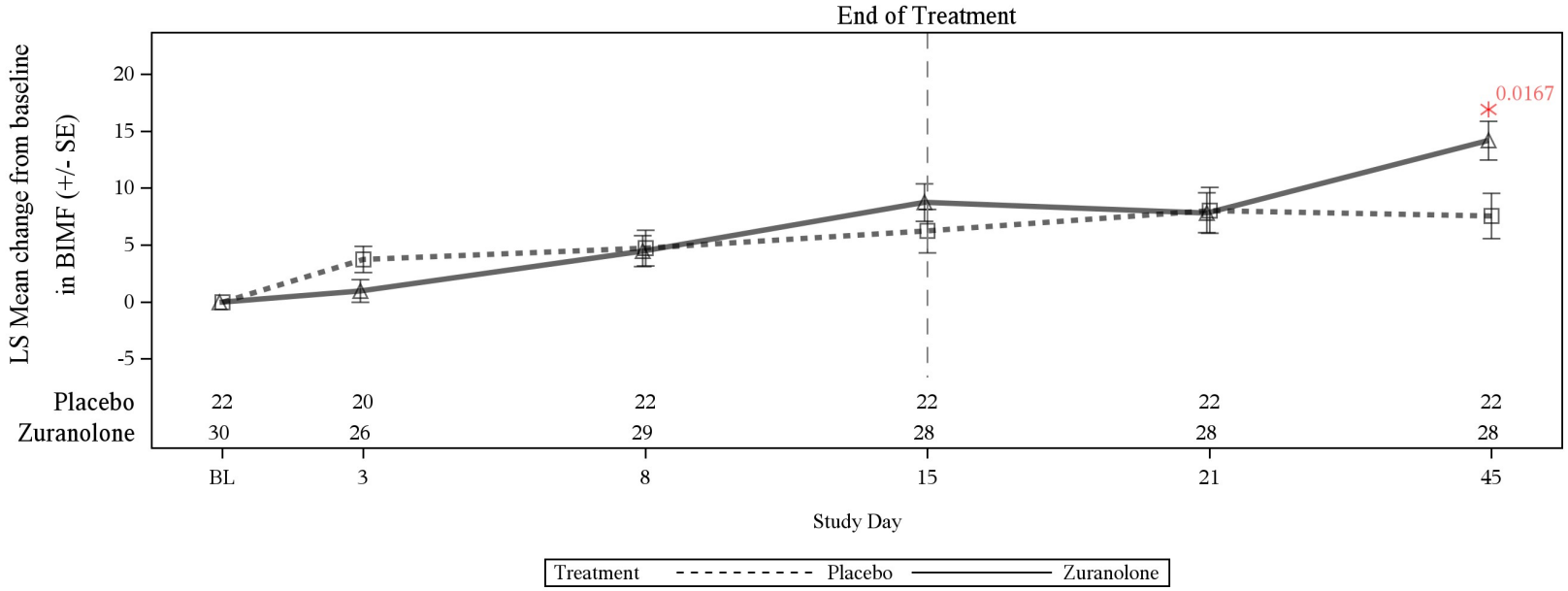
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

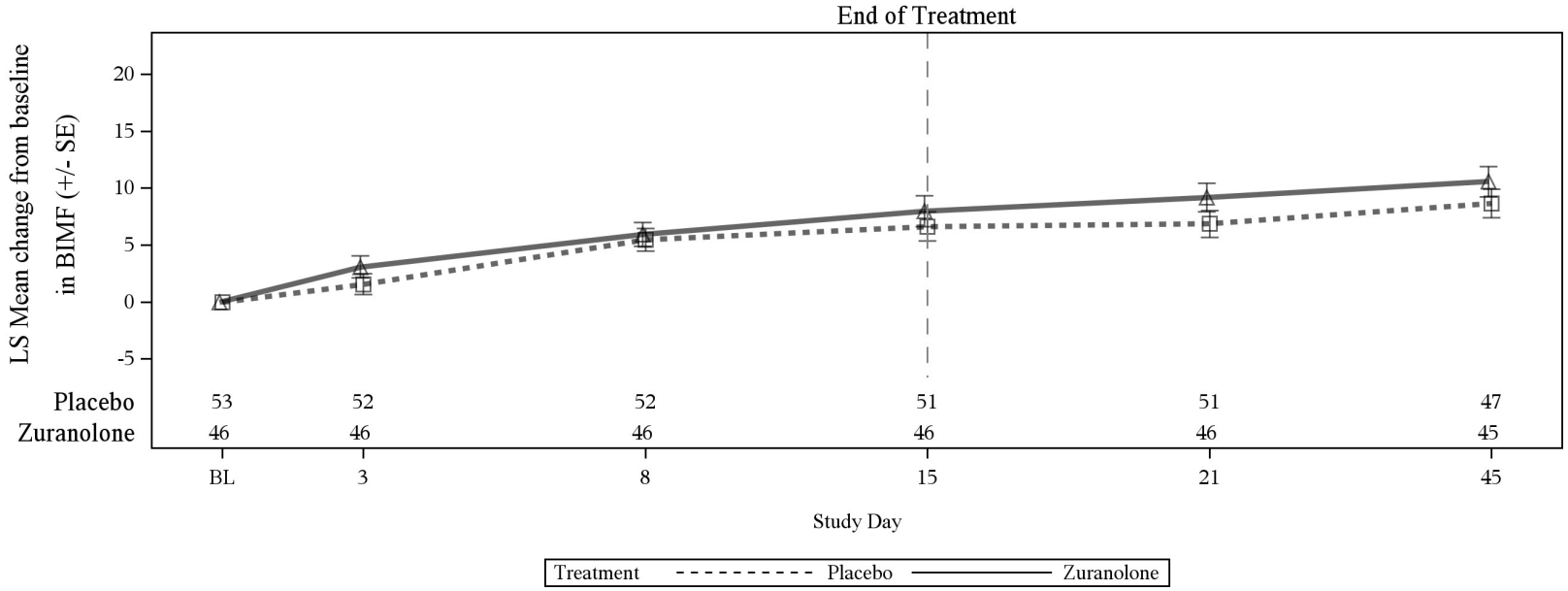
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

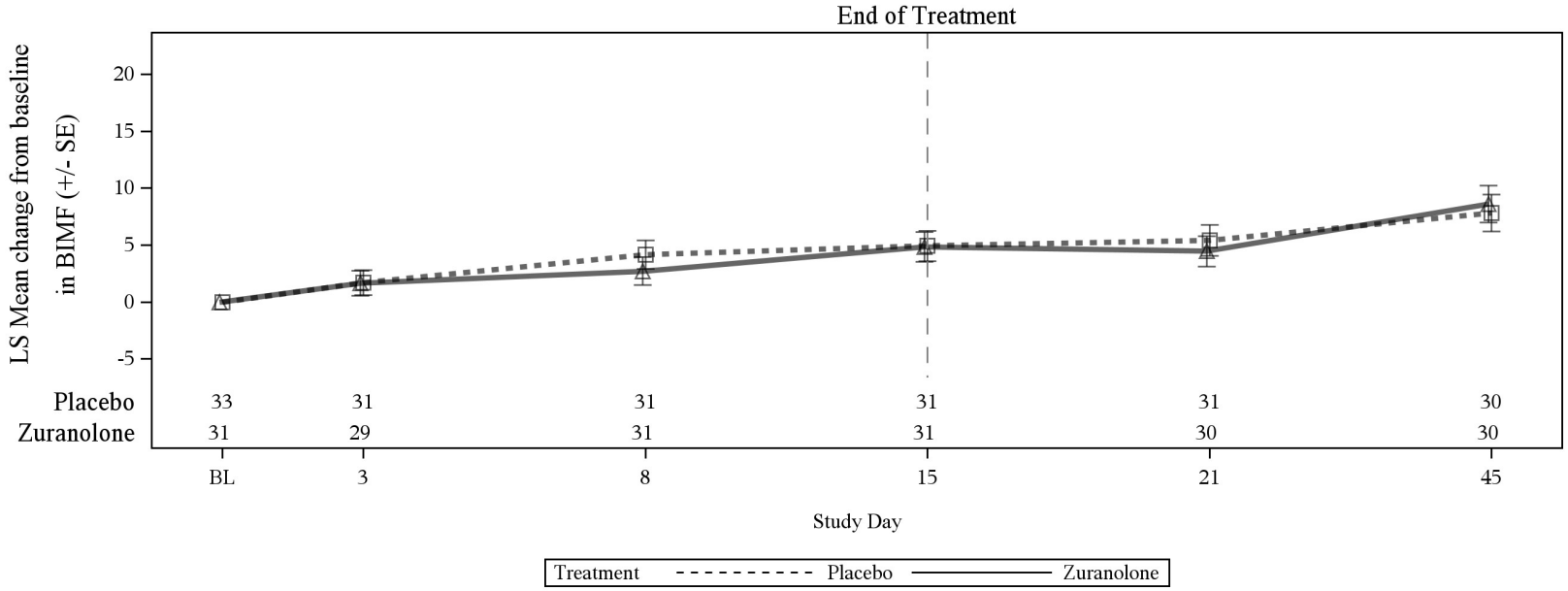
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

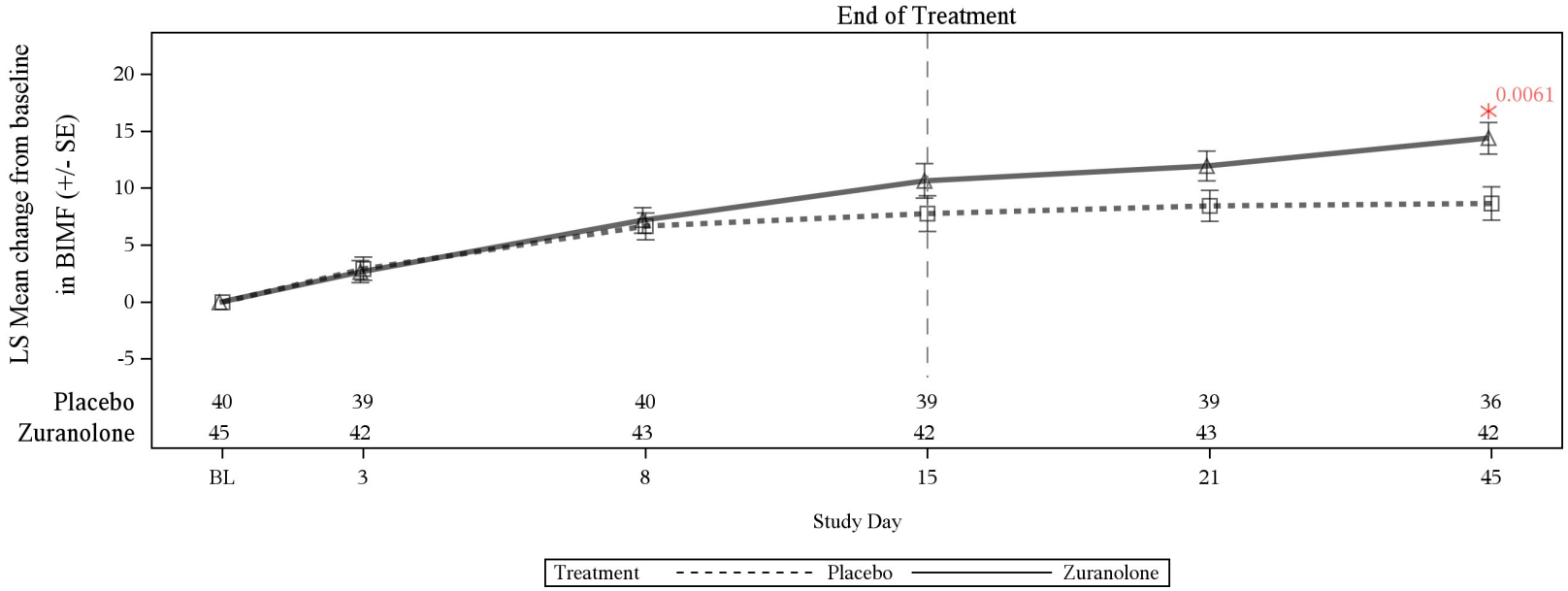
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Source: biib125/v_a/germany_amnog/f-bimf-comp-mmrm-201-by.sas:f-bimf-comp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

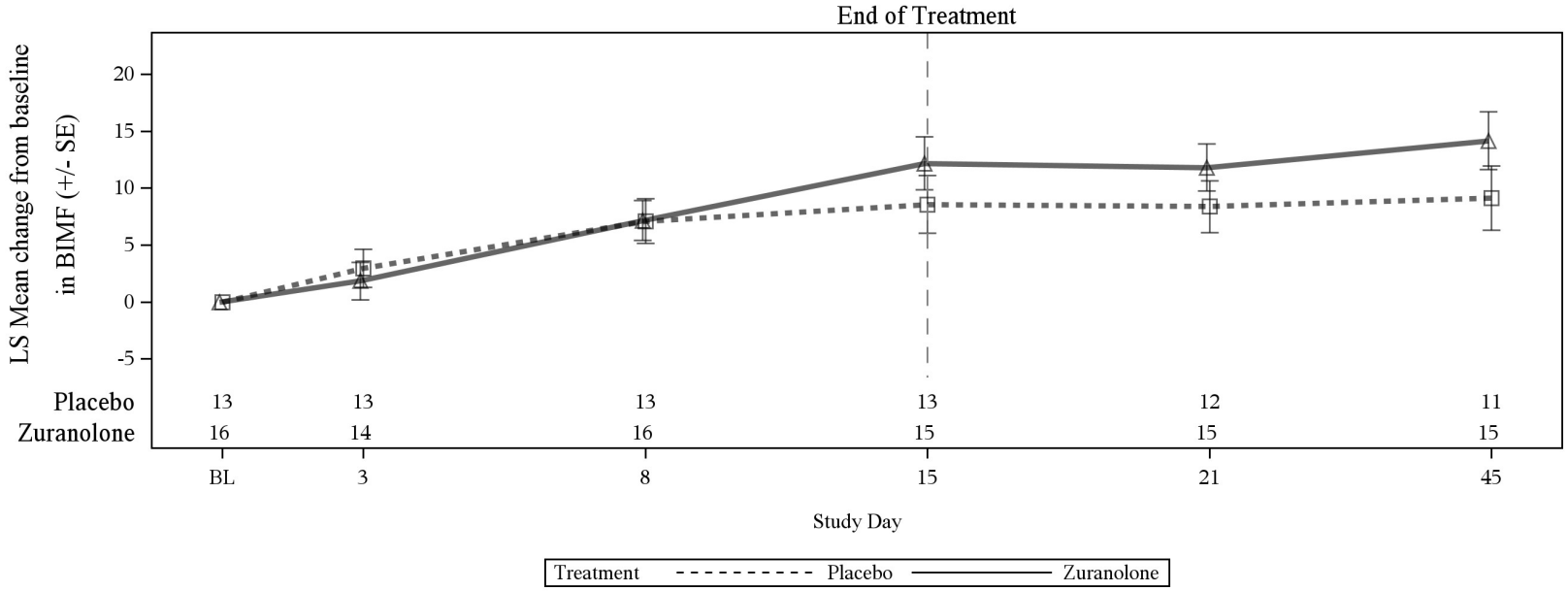
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

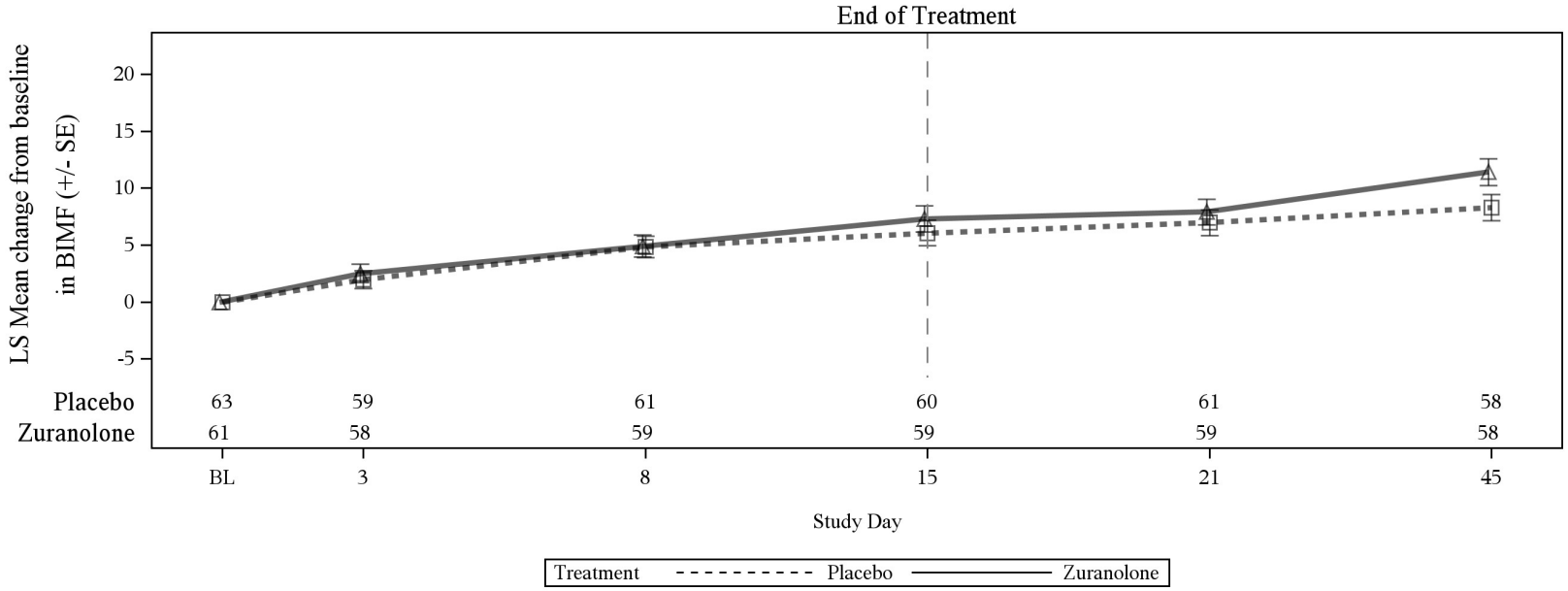
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

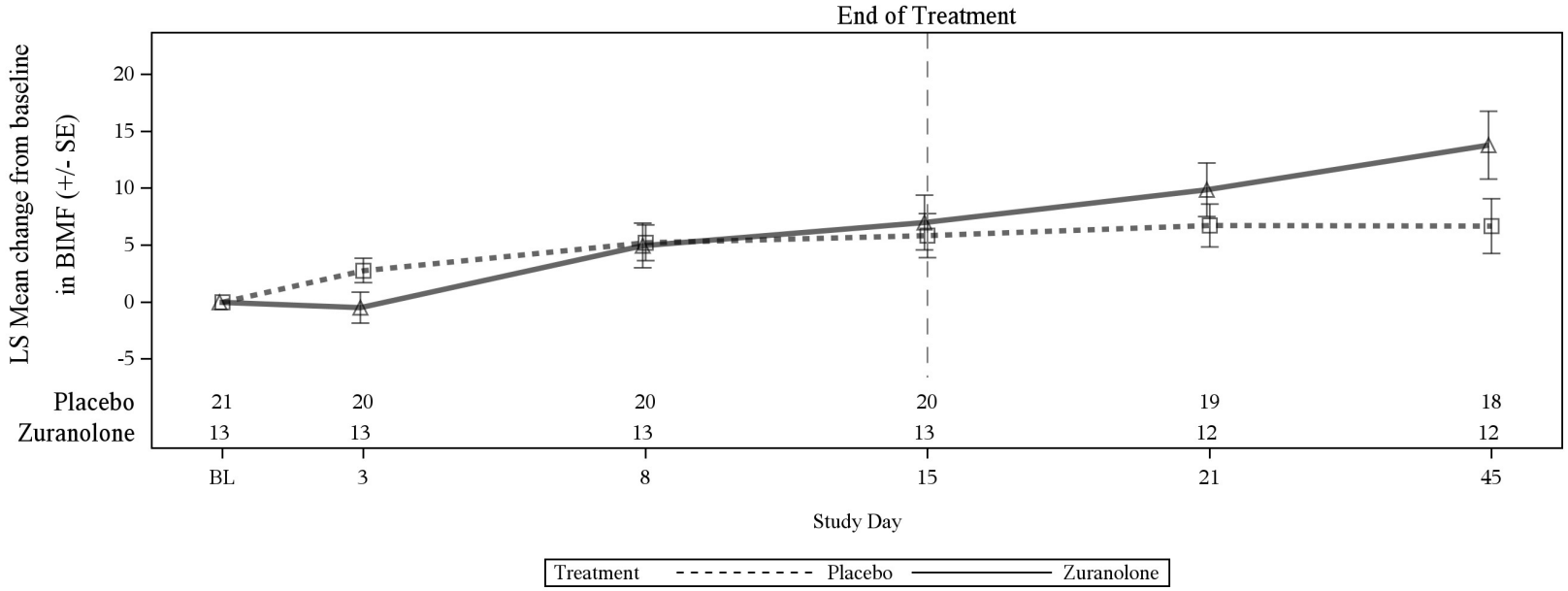
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

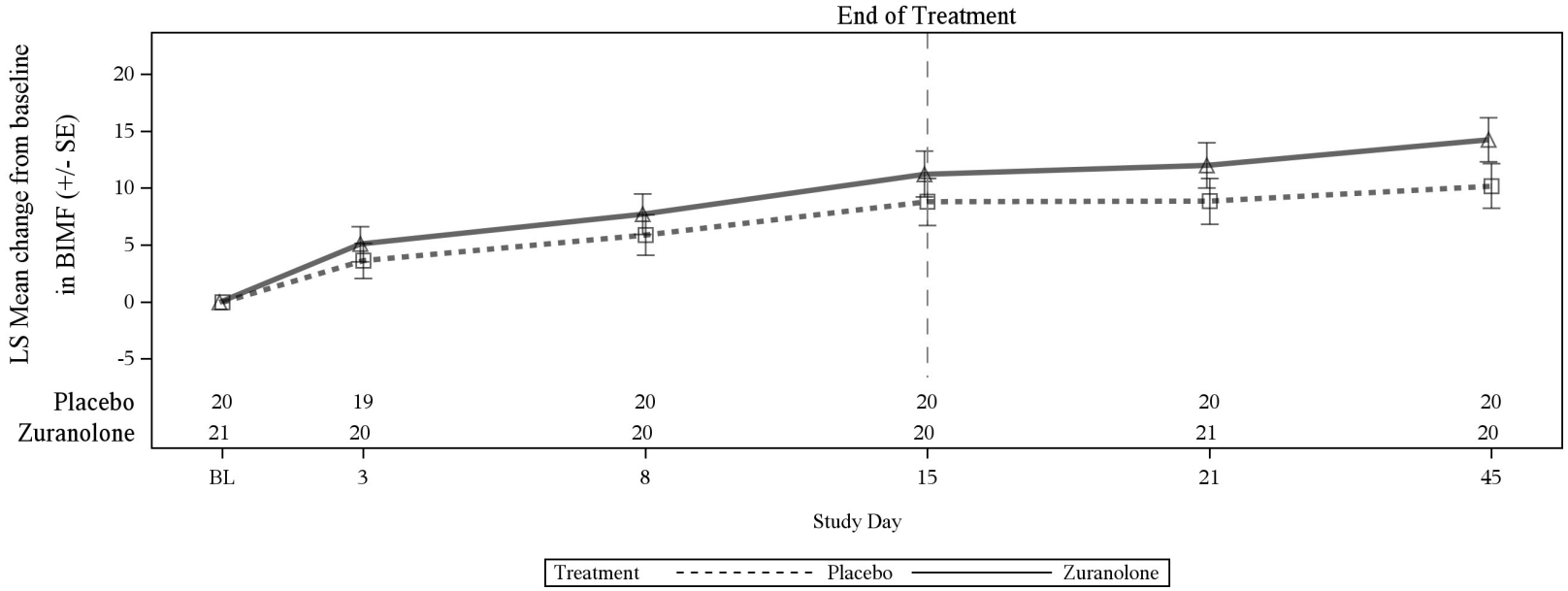
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

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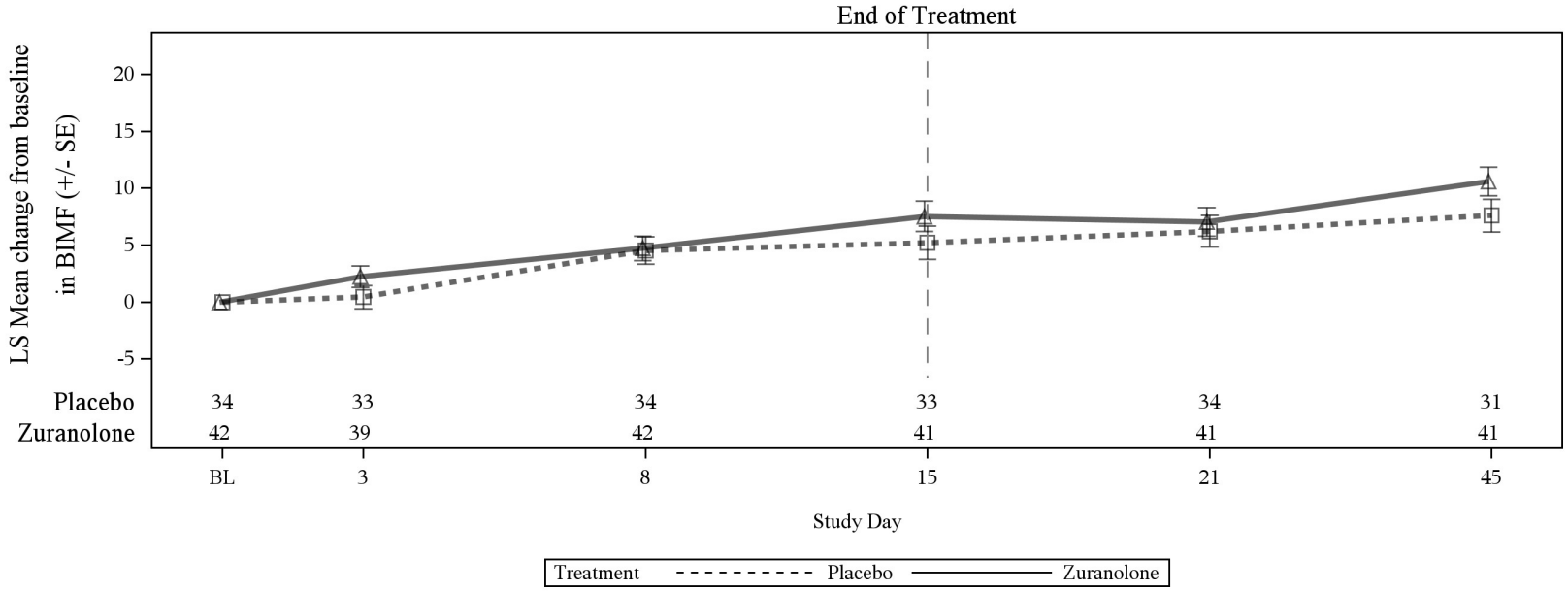
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Source: biib125/v_a/germany_amnog/f-bimf-comp-mmrm-201-by.sas:f-bimf-comp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

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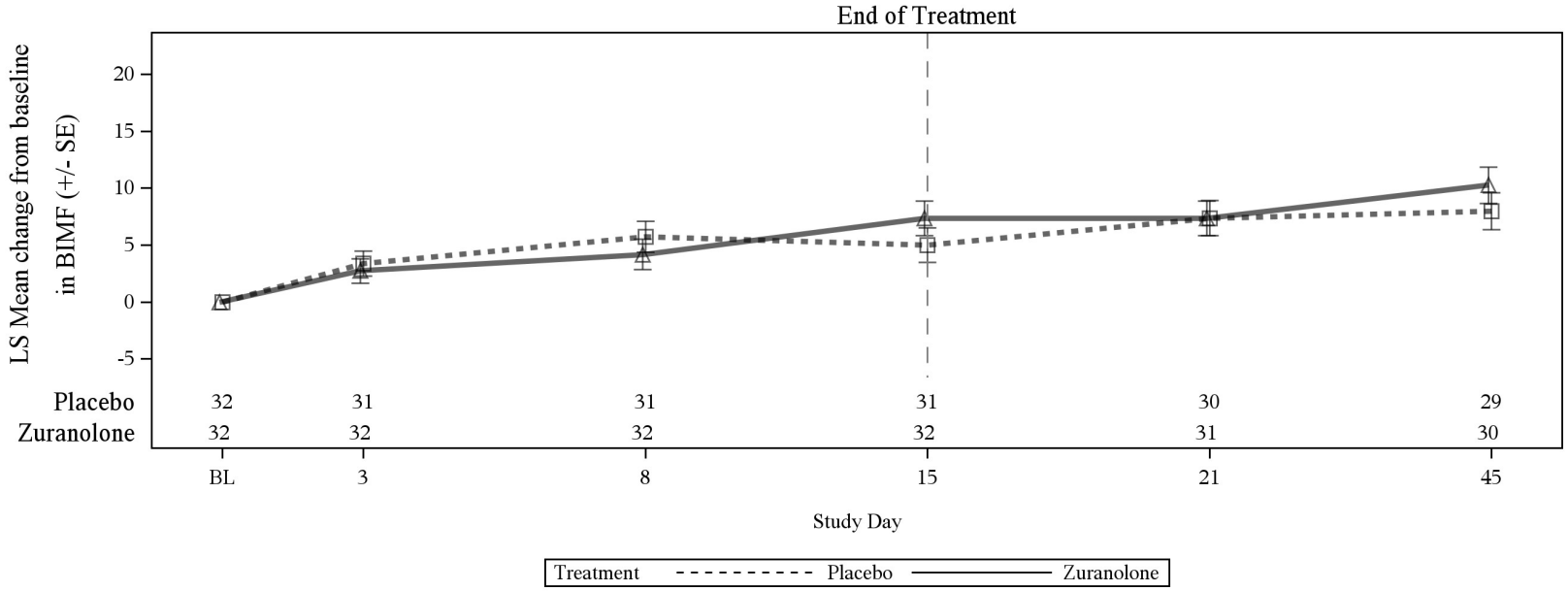
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

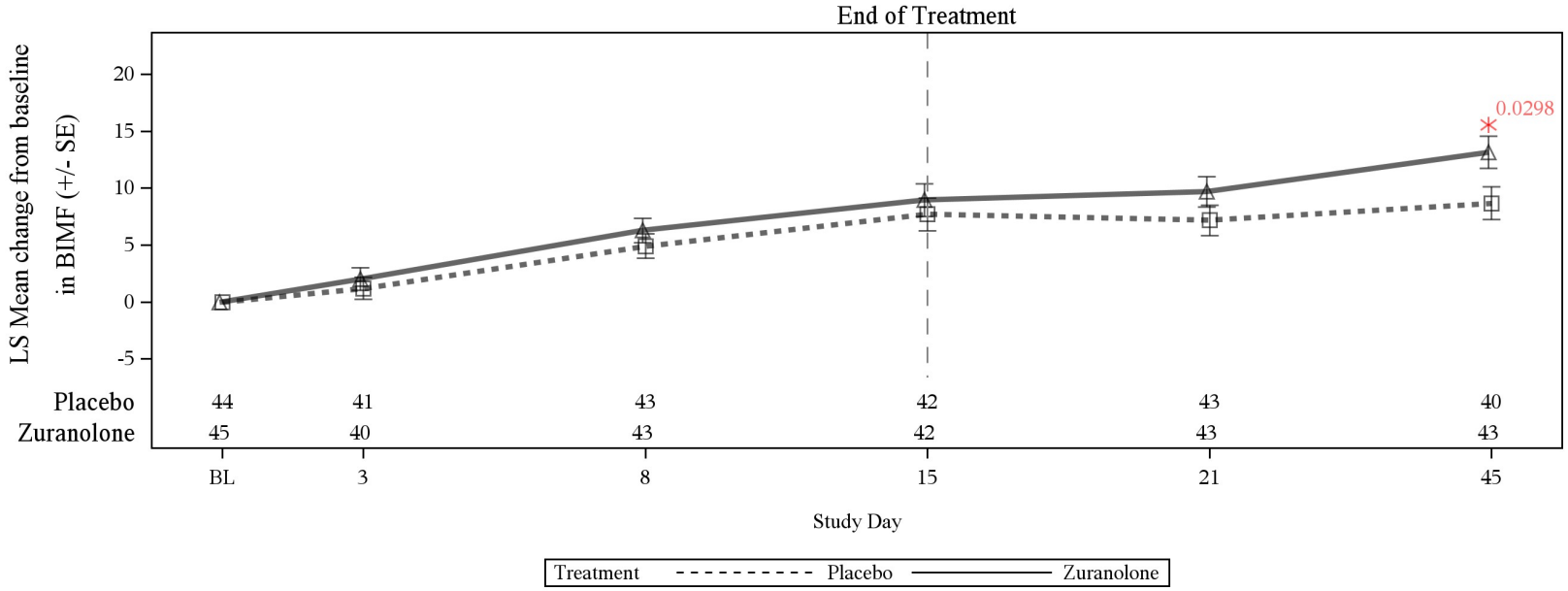
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

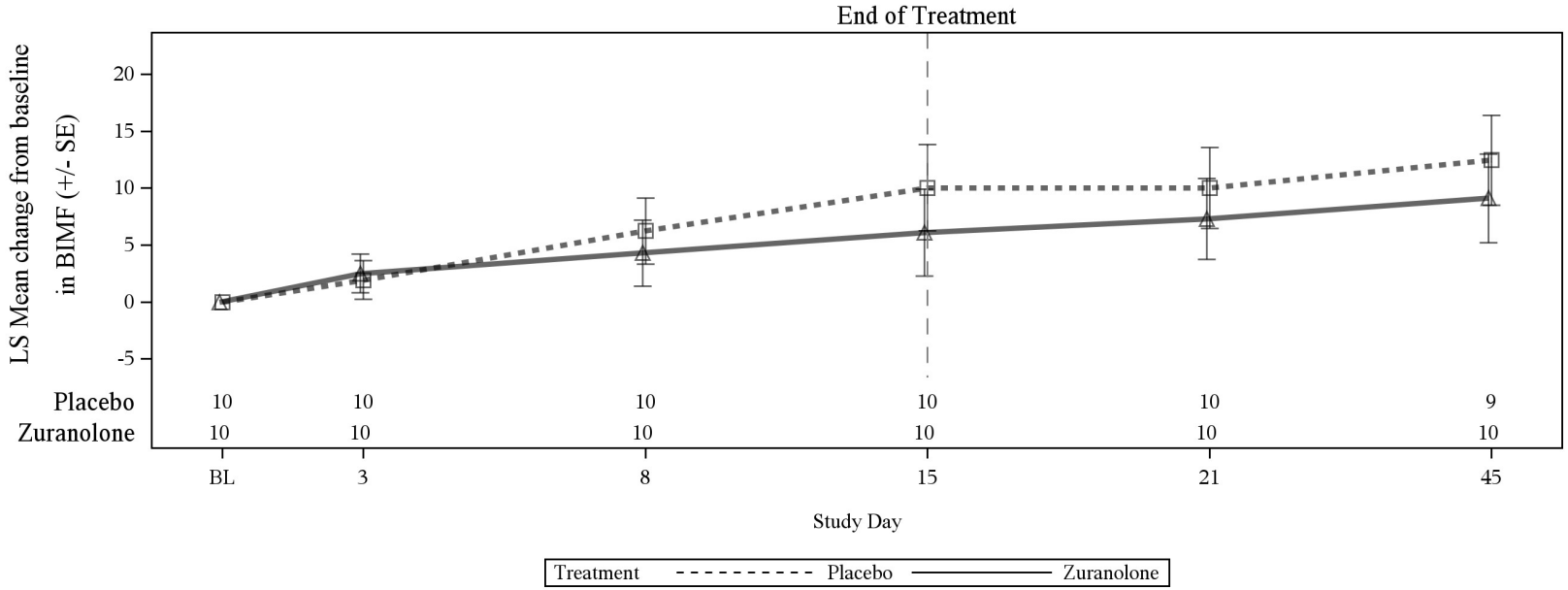
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

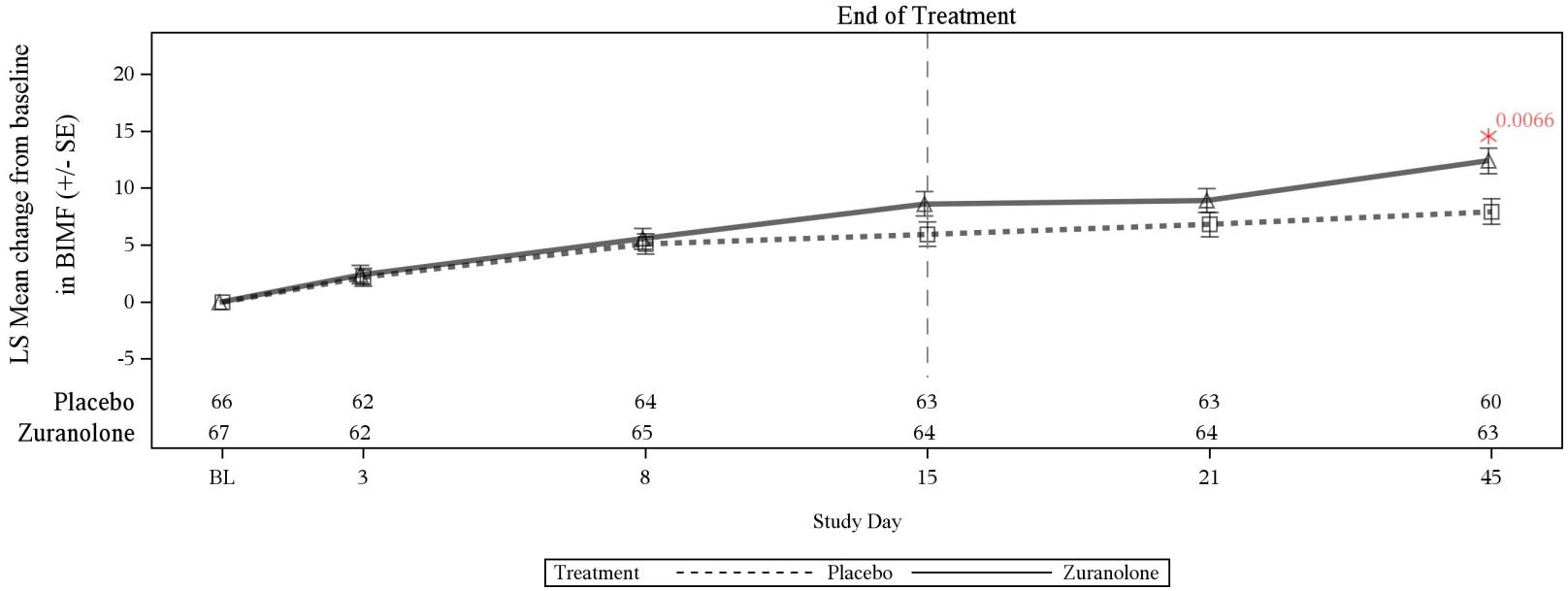
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

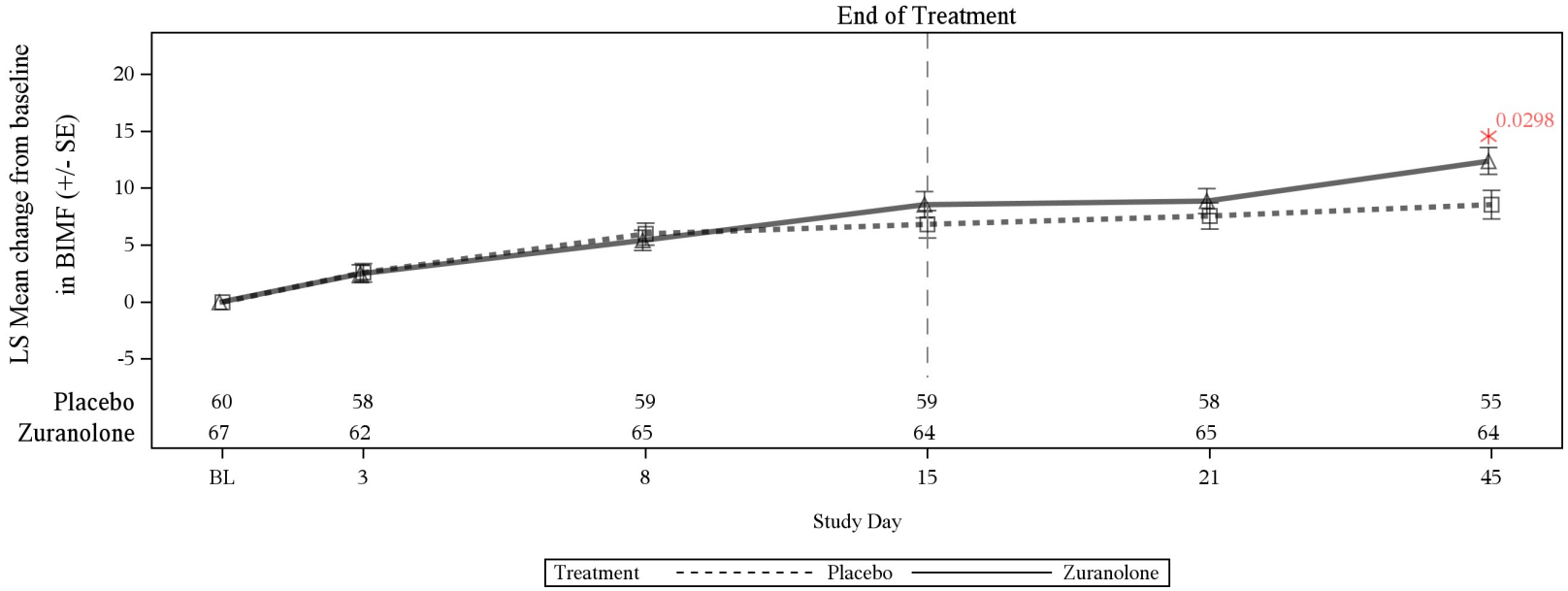
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

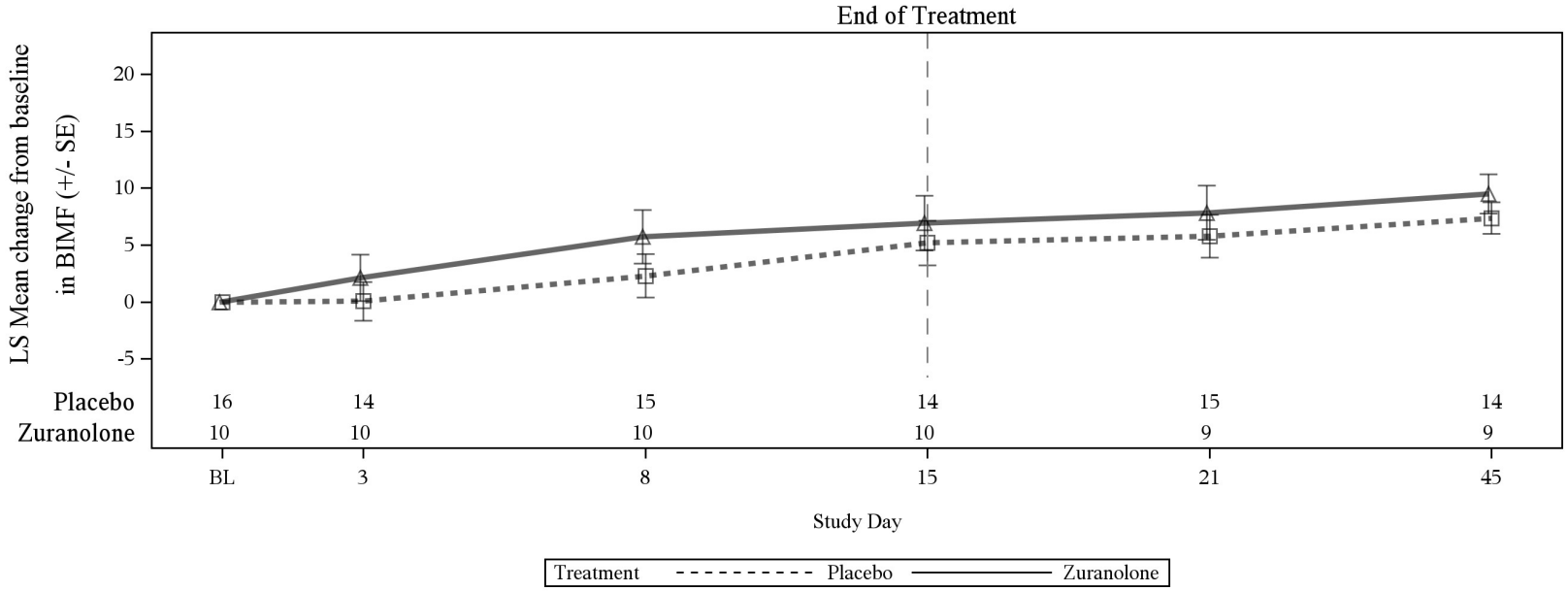
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Score by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-comp-mmrm-201-by.sas:f-bimf-comp-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

3.2.2 Ansprechen

3.2.2.1 Responder-Analysen

3.2.2.1 .1 ITT-Population

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with a response, n (%) [2]	8 (10.7)	7 (9.2)
Number of subjects with missing evaluation, n (%)	3 (4.0)	4 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.703
95% CI for the RR		(0.280, 1.766)
p-value for RR		0.4536
OR - Odds Ratio (Zuranolone vs. Placebo)		0.525
95% CI for the OR		(0.162, 1.696)
p-value for OR		0.2814
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-ovr.sas:t-bimf-comp-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with a response, n (%) [2]	14 (18.7)	18 (23.7)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.033
95% CI for the RR		(0.593, 1.800)
p-value for RR		0.9078
OR - Odds Ratio (Zuranolone vs. Placebo)		0.872
95% CI for the OR		(0.377, 2.019)
p-value for OR		0.7493
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-ovr.sas:t-bimf-comp-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with a response, n (%) [2]	19 (25.3)	27 (35.5)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.142
95% CI for the RR		(0.725, 1.800)
p-value for RR		0.5668
OR - Odds Ratio (Zuranolone vs. Placebo)		1.084
95% CI for the OR		(0.487, 2.410)
p-value for OR		0.8438
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-ovr.sas:t-bimf-comp-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with a response, n (%) [2]	21 (28.0)	31 (40.8)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.186
95% CI for the RR		(0.783, 1.798)
p-value for RR		0.4206
OR - Odds Ratio (Zuranolone vs. Placebo)		1.221
95% CI for the OR		(0.568, 2.624)
p-value for OR		0.6092
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-ovr.sas:t-bimf-comp-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	24 (32.0)	41 (53.9)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.373
95% CI for the RR		(0.921, 2.046)
p-value for RR		0.1194
OR - Odds Ratio (Zuranolone vs. Placebo)		1.948
95% CI for the OR		(0.889, 4.269)
p-value for OR		0.0959
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-ovr.sas:t-bimf-comp-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.2.2.1 .2 Subgruppen

3.2.2.1 .2 .1 Interaktionstest

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	19 (25.3)	27 (35.5)	
Number of subjects with response at Day 45, n (%)	24 (32.0)	41 (53.9)	
Age Group (years)			0.2338
Day 15			
18 - 24, n / N (%)	7/25 (28.0)	5/17 (29.4)	
25 - 45, n / N (%)	12/50 (24.0)	22/59 (37.3)	
Day 45			
18 - 24, n / N (%)	9/25 (36.0)	10/17 (58.8)	
25 - 45, n / N (%)	15/50 (30.0)	31/59 (52.5)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-int.sas:t-bimf-comp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.2223
Day 15			
<28, n / N (%)	7/22 (31.8)	12/30 (40.0)	
>=28, n / N (%)	12/53 (22.6)	15/46 (32.6)	
Day 45			
<28, n / N (%)	8/22 (36.4)	18/30 (60.0)	
>=28, n / N (%)	16/53 (30.2)	23/46 (50.0)	
Race Group (Black or African American, White)			0.0892
Day 15			
Black or African American, n / N (%)	8/32 (25.0)	5/31 (16.1)	
White, n / N (%)	9/40 (22.5)	22/44 (50.0)	
Day 45			
Black or African American, n / N (%)	11/32 (34.4)	13/31 (41.9)	
White, n / N (%)	11/40 (27.5)	28/44 (63.6)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-int.sas:t-bimf-comp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.4340
Day 15			
Yes, n / N (%)	4/13 (30.8)	10/16 (62.5)	
No, n / N (%)	15/62 (24.2)	17/60 (28.3)	
Day 45			
Yes, n / N (%)	4/13 (30.8)	9/16 (56.3)	
No, n / N (%)	20/62 (32.3)	32/60 (53.3)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-int.sas:t-bimf-comp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.2679(a) 0.5156(b) 0.4894(c)
Day 15			
<=24.9, n / N (%)	2/21 (9.5)	4/13 (30.8)	
25-29.9, n / N (%)	8/20 (40.0)	7/21 (33.3)	
>=30, n / N (%)	9/34 (26.5)	16/42 (38.1)	
Day 45			
<=24.9, n / N (%)	4/21 (19.0)	7/13 (53.8)	
25-29.9, n / N (%)	9/20 (45.0)	10/21 (47.6)	
>=30, n / N (%)	11/34 (32.4)	24/42 (57.1)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-int.sas:t-bimf-comp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.7906
Day 15			
3rd Trimester, n / N (%)	7/32 (21.9)	8/32 (25.0)	
Postpartum, n / N (%)	12/43 (27.9)	19/44 (43.2)	
Day 45			
3rd Trimester, n / N (%)	10/32 (31.3)	15/32 (46.9)	
Postpartum, n / N (%)	14/43 (32.6)	26/44 (59.1)	
Family History of PPD			0.9940
Day 15			
Yes, n / N (%)	4/10 (40.0)	4/10 (40.0)	
No/Unknown, n / N (%)	15/65 (23.1)	23/66 (34.8)	
Day 45			
Yes, n / N (%)	2/10 (20.0)	3/10 (30.0)	
No/Unknown, n / N (%)	22/65 (33.8)	38/66 (57.6)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-int.sas:t-bimf-comp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.7300
Day 15			
1st Episode, n / N (%)	16/59 (27.1)	24/66 (36.4)	
Recurrent Episode, n / N (%)	3/16 (18.8)	3/10 (30.0)	
Day 45			
1st Episode, n / N (%)	19/59 (32.2)	38/66 (57.6)	
Recurrent Episode, n / N (%)	5/16 (31.3)	3/10 (30.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	2/8 (25.0)	4/10 (40.0)	
>=20, n / N (%)	17/67 (25.4)	23/66 (34.8)	
Day 45			
<20, n / N (%)	2/8 (25.0)	7/10 (70.0)	
>=20, n / N (%)	22/67 (32.8)	34/66 (51.5)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-int.sas:t-bimf-comp-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

3.2.2.1 .2 .2 Subgruppenanalysen

3.2.2.1 .2 .2 .1 Alter

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 3		
Number of subjects with a response, n (%) [2]	3 (12.0)	2 (11.8)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.559
95% CI for the RR		(0.128, 2.442)
p-value for RR		0.4392
Day 8		
Number of subjects with a response, n (%) [2]	6 (24.0)	5 (29.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.698
95% CI for the RR		(0.303, 1.608)
p-value for RR		0.3987

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 15		
Number of subjects with a response, n (%) [2]	7 (28.0)	5 (29.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.599
95% CI for the RR		(0.235, 1.523)
p-value for RR		0.2814
Day 21		
Number of subjects with a response, n (%) [2]	8 (32.0)	7 (41.2)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.733
95% CI for the RR		(0.336, 1.601)
p-value for RR		0.4362

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 45		
Number of subjects with a response, n (%) [2]	9 (36.0)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.931
95% CI for the RR		(0.466, 1.862)
p-value for RR		0.8401

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 3		
Number of subjects with a response, n (%) [2]	5 (10.0)	5 (8.5)
Number of subjects with missing evaluation, n (%)	3 (6.0)	3 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.753
95% CI for the RR		(0.240, 2.358)
p-value for RR		0.6257
Day 8		
Number of subjects with a response, n (%) [2]	8 (16.0)	13 (22.0)
Number of subjects with missing evaluation, n (%)	1 (2.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.223
95% CI for the RR		(0.602, 2.484)
p-value for RR		0.5778

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 15		
Number of subjects with a response, n (%) [2]	12 (24.0)	22 (37.3)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.380
95% CI for the RR		(0.805, 2.364)
p-value for RR		0.2414
Day 21		
Number of subjects with a response, n (%) [2]	13 (26.0)	24 (40.7)
Number of subjects with missing evaluation, n (%)	2 (4.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.389
95% CI for the RR		(0.835, 2.311)
p-value for RR		0.2052

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 45		
Number of subjects with a response, n (%) [2]	15 (30.0)	31 (52.5)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.555
95% CI for the RR		(0.948, 2.552)
p-value for RR		0.0804

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

3.2.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 3		
Number of subjects with a response, n (%) [2]	2 (9.1)	3 (10.0)
Number of subjects with missing evaluation, n (%)	2 (9.1)	4 (13.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.646
95% CI for the RR		(0.118, 3.540)
p-value for RR		0.6151
Day 8		
Number of subjects with a response, n (%) [2]	3 (13.6)	9 (30.0)
Number of subjects with missing evaluation, n (%)	0	1 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.293
95% CI for the RR		(0.423, 3.955)
p-value for RR		0.6524

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 15		
Number of subjects with a response, n (%) [2]	7 (31.8)	12 (40.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.739
95% CI for the RR		(0.362, 1.506)
p-value for RR		0.4050
Day 21		
Number of subjects with a response, n (%) [2]	8 (36.4)	10 (33.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.539
95% CI for the RR		(0.261, 1.111)
p-value for RR		0.0938

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 3 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 45		
Number of subjects with a response, n (%) [2]	8 (36.4)	18 (60.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.970
95% CI for the RR		(0.526, 1.788)
p-value for RR		0.9215

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 3		
Number of subjects with a response, n (%) [2]	6 (11.3)	4 (8.7)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.714
95% CI for the RR		(0.228, 2.234)
p-value for RR		0.5630
Day 8		
Number of subjects with a response, n (%) [2]	11 (20.8)	9 (19.6)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.877
95% CI for the RR		(0.433, 1.777)
p-value for RR		0.7150

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 15		
Number of subjects with a response, n (%) [2]	12 (22.6)	15 (32.6)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.339
95% CI for the RR		(0.749, 2.394)
p-value for RR		0.3241
Day 21		
Number of subjects with a response, n (%) [2]	13 (24.5)	21 (45.7)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.731
95% CI for the RR		(1.032, 2.904)
p-value for RR		0.0376

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 45		
Number of subjects with a response, n (%) [2]	16 (30.2)	23 (50.0)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.540
95% CI for the RR		(0.925, 2.565)
p-value for RR		0.0969

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

3.2.2.1 .2 .2 .3 Abstammung

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 3		
Number of subjects with a response, n (%) [2]	3 (9.4)	1 (3.2)
Number of subjects with missing evaluation, n (%)	1 (3.1)	2 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.296
95% CI for the RR		(0.035, 2.510)
p-value for RR		0.2644
Day 8		
Number of subjects with a response, n (%) [2]	6 (18.8)	5 (16.1)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.740
95% CI for the RR		(0.259, 2.117)
p-value for RR		0.5750

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 2 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 15		
Number of subjects with a response, n (%) [2]	8 (25.0)	5 (16.1)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.555
95% CI for the RR		(0.210, 1.467)
p-value for RR		0.2353
Day 21		
Number of subjects with a response, n (%) [2]	7 (21.9)	4 (12.9)
Number of subjects with missing evaluation, n (%)	1 (3.1)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.508
95% CI for the RR		(0.164, 1.571)
p-value for RR		0.2396

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 45		
Number of subjects with a response, n (%) [2]	11 (34.4)	13 (41.9)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.050
95% CI for the RR		(0.578, 1.908)
p-value for RR		0.8724

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 4 of 6

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 3		
Number of subjects with a response, n (%) [2]	5 (12.5)	5 (11.4)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.728
95% CI for the RR		(0.233, 2.274)
p-value for RR		0.5852
Day 8		
Number of subjects with a response, n (%) [2]	8 (20.0)	13 (29.5)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.183
95% CI for the RR		(0.592, 2.365)
p-value for RR		0.6337

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	9 (22.5)	22 (50.0)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.780
95% CI for the RR		(0.963, 3.290)
p-value for RR		0.0657
Day 21		
Number of subjects with a response, n (%) [2]	12 (30.0)	27 (61.4)
Number of subjects with missing evaluation, n (%)	1 (2.5)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.639
95% CI for the RR		(1.029, 2.610)
p-value for RR		0.0376

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	11 (27.5)	28 (63.6)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.854
95% CI for the RR		(1.065, 3.226)
p-value for RR		0.0291

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

3.2.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 3		
Number of subjects with a response, n (%) [2]	3 (23.1)	1 (6.3)
Number of subjects with missing evaluation, n (%)	0	2 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.248
95% CI for the RR		(0.030, 2.024)
p-value for RR		0.1931
Day 8		
Number of subjects with a response, n (%) [2]	4 (30.8)	7 (43.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.304
95% CI for the RR		(0.555, 3.061)
p-value for RR		0.5426

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 15		
Number of subjects with a response, n (%) [2]	4 (30.8)	10 (62.5)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.862
95% CI for the RR		(0.844, 4.112)
p-value for RR		0.1238
Day 21		
Number of subjects with a response, n (%) [2]	5 (38.5)	9 (56.3)
Number of subjects with missing evaluation, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.341
95% CI for the RR		(0.597, 3.014)
p-value for RR		0.4778

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 45		
Number of subjects with a response, n (%) [2]	4 (30.8)	9 (56.3)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.676
95% CI for the RR		(0.646, 4.349)
p-value for RR		0.2884

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 3		
Number of subjects with a response, n (%) [2]	5 (8.1)	6 (10.0)
Number of subjects with missing evaluation, n (%)	3 (4.8)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.986
95% CI for the RR		(0.331, 2.934)
p-value for RR		0.9792
Day 8		
Number of subjects with a response, n (%) [2]	10 (16.1)	11 (18.3)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.903
95% CI for the RR		(0.440, 1.857)
p-value for RR		0.7824

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 15		
Number of subjects with a response, n (%) [2]	15 (24.2)	17 (28.3)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.931
95% CI for the RR		(0.525, 1.649)
p-value for RR		0.8059
Day 21		
Number of subjects with a response, n (%) [2]	16 (25.8)	22 (36.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.129
95% CI for the RR		(0.696, 1.833)
p-value for RR		0.6227

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 45		
Number of subjects with a response, n (%) [2]	20 (32.3)	32 (53.3)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.314
95% CI for the RR		(0.852, 2.027)
p-value for RR		0.2165

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

3.2.2.1 .2 .2 .5 BMI

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 3		
Number of subjects with a response, n (%) [2]	1 (4.8)	1 (7.7)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.128
95% CI for the RR		(0.078, 16.241)
p-value for RR		0.9297
Day 8		
Number of subjects with a response, n (%) [2]	3 (14.3)	3 (23.1)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.128
95% CI for the RR		(0.307, 4.140)
p-value for RR		0.8565

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 15		
Number of subjects with a response, n (%) [2]	2 (9.5)	4 (30.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.255
95% CI for the RR		(0.524, 9.710)
p-value for RR		0.2750
Day 21		
Number of subjects with a response, n (%) [2]	4 (19.0)	5 (38.5)
Number of subjects with missing evaluation, n (%)	2 (9.5)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.409
95% CI for the RR		(0.605, 3.283)
p-value for RR		0.4264

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 45		
Number of subjects with a response, n (%) [2]	4 (19.0)	7 (53.8)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.973
95% CI for the RR		(0.669, 5.822)
p-value for RR		0.2183

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 3		
Number of subjects with a response, n (%) [2]	5 (25.0)	3 (14.3)
Number of subjects with missing evaluation, n (%)	1 (5.0)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.525
95% CI for the RR		(0.170, 1.620)
p-value for RR		0.2624
Day 8		
Number of subjects with a response, n (%) [2]	6 (30.0)	6 (28.6)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.875
95% CI for the RR		(0.405, 1.889)
p-value for RR		0.7339

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	8 (40.0)	7 (33.3)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.766
95% CI for the RR		(0.405, 1.448)
p-value for RR		0.4116
Day 21		
Number of subjects with a response, n (%) [2]	7 (35.0)	10 (47.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.250
95% CI for the RR		(0.586, 2.667)
p-value for RR		0.5637

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 45		
Number of subjects with a response, n (%) [2]	9 (45.0)	10 (47.6)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.972
95% CI for the RR		(0.518, 1.825)
p-value for RR		0.9304

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 3		
Number of subjects with a response, n (%) [2]	2 (5.9)	3 (7.1)
Number of subjects with missing evaluation, n (%)	1 (2.9)	3 (7.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.009
95% CI for the RR		(0.181, 5.615)
p-value for RR		0.9922
Day 8		
Number of subjects with a response, n (%) [2]	5 (14.7)	9 (21.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.210
95% CI for the RR		(0.485, 3.023)
p-value for RR		0.6827

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 15		
Number of subjects with a response, n (%) [2]	9 (26.5)	16 (38.1)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.195
95% CI for the RR		(0.632, 2.259)
p-value for RR		0.5826
Day 21		
Number of subjects with a response, n (%) [2]	10 (29.4)	16 (38.1)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.076
95% CI for the RR		(0.587, 1.974)
p-value for RR		0.8132

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 45		
Number of subjects with a response, n (%) [2]	11 (32.4)	24 (57.1)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.467
95% CI for the RR		(0.850, 2.533)
p-value for RR		0.1690

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

3.2.2.1 .2 .2 .6 Beginn der PPD

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 3		
Number of subjects with a response, n (%) [2]	3 (9.4)	5 (15.6)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.521
95% CI for the RR		(0.406, 5.691)
p-value for RR		0.5335
Day 8		
Number of subjects with a response, n (%) [2]	7 (21.9)	6 (18.8)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.782
95% CI for the RR		(0.321, 1.908)
p-value for RR		0.5891

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 15		
Number of subjects with a response, n (%) [2]	7 (21.9)	8 (25.0)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.043
95% CI for the RR		(0.424, 2.565)
p-value for RR		0.9272
Day 21		
Number of subjects with a response, n (%) [2]	9 (28.1)	8 (25.0)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.811
95% CI for the RR		(0.394, 1.668)
p-value for RR		0.5693

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 45		
Number of subjects with a response, n (%) [2]	10 (31.3)	15 (46.9)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.369
95% CI for the RR		(0.700, 2.677)
p-value for RR		0.3590

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 3		
Number of subjects with a response, n (%) [2]	5 (11.6)	2 (4.5)
Number of subjects with missing evaluation, n (%)	2 (4.7)	4 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.299
95% CI for the RR		(0.065, 1.383)
p-value for RR		0.1223
Day 8		
Number of subjects with a response, n (%) [2]	7 (16.3)	12 (27.3)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.282
95% CI for the RR		(0.617, 2.663)
p-value for RR		0.5051

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	12 (27.9)	19 (43.2)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.184
95% CI for the RR		(0.714, 1.964)
p-value for RR		0.5126
Day 21		
Number of subjects with a response, n (%) [2]	12 (27.9)	23 (52.3)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.433
95% CI for the RR		(0.848, 2.422)
p-value for RR		0.1786

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	14 (32.6)	26 (59.1)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.389
95% CI for the RR		(0.846, 2.279)
p-value for RR		0.1936

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

3.2.2.1 .2 .2 .7 PPD in der Familie

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 3		
Number of subjects with a response, n (%) [2]	1 (10.0)	0
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.015, 7.323)
p-value for RR		0.4858
Day 8		
Number of subjects with a response, n (%) [2]	3 (30.0)	0
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.14
95% CI for the RR		(0.008, 2.452)
p-value for RR		0.1797

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	4 (40.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.342, 2.926)
p-value for RR		1.0000
Day 21		
Number of subjects with a response, n (%) [2]	5 (50.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.80
95% CI for the RR		(0.300, 2.132)
p-value for RR		0.6554

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	2 (20.0)	3 (30.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.50
95% CI for the RR		(0.315, 7.137)
p-value for RR		0.6104

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 3		
Number of subjects with a response, n (%) [2]	7 (10.8)	7 (10.6)
Number of subjects with missing evaluation, n (%)	3 (4.6)	4 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.98
95% CI for the RR		(0.366, 2.651)
p-value for RR		0.9759
Day 8		
Number of subjects with a response, n (%) [2]	11 (16.9)	18 (27.3)
Number of subjects with missing evaluation, n (%)	1 (1.5)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.61
95% CI for the RR		(0.827, 3.141)
p-value for RR		0.1610

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	15 (23.1)	23 (34.8)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.51
95% CI for the RR		(0.869, 2.625)
p-value for RR		0.1441
Day 21		
Number of subjects with a response, n (%) [2]	16 (24.6)	27 (40.9)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.66
95% CI for the RR		(0.993, 2.781)
p-value for RR		0.0531

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	22 (33.8)	38 (57.6)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.70
95% CI for the RR		(1.143, 2.533)
p-value for RR		0.0089

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

3.2.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 3		
Number of subjects with a response, n (%) [2]	7 (11.9)	7 (10.6)
Number of subjects with missing evaluation, n (%)	1 (1.7)	4 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.89
95% CI for the RR		(0.333, 2.399)
p-value for RR		0.8238
Day 8		
Number of subjects with a response, n (%) [2]	12 (20.3)	17 (25.8)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.27
95% CI for the RR		(0.661, 2.426)
p-value for RR		0.4765

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	16 (27.1)	24 (36.4)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.34
95% CI for the RR		(0.792, 2.269)
p-value for RR		0.2745
Day 21		
Number of subjects with a response, n (%) [2]	17 (28.8)	27 (40.9)
Number of subjects with missing evaluation, n (%)	1 (1.7)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.42
95% CI for the RR		(0.866, 2.329)
p-value for RR		0.1651

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	19 (32.2)	38 (57.6)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.79
95% CI for the RR		(1.170, 2.733)
p-value for RR		0.0073

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 3		
Number of subjects with a response, n (%) [2]	1 (6.3)	0
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.52
95% CI for the RR		(0.023, 11.544)
p-value for RR		0.6759
Day 8		
Number of subjects with a response, n (%) [2]	2 (12.5)	1 (10.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.80
95% CI for the RR		(0.083, 7.718)
p-value for RR		0.8470

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	3 (18.8)	3 (30.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.60
95% CI for the RR		(0.398, 6.434)
p-value for RR		0.5080
Day 21		
Number of subjects with a response, n (%) [2]	4 (25.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.60
95% CI for the RR		(0.512, 4.996)
p-value for RR		0.4185

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	5 (31.3)	3 (30.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.96
95% CI for the RR		(0.291, 3.167)
p-value for RR		0.9466

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response (9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

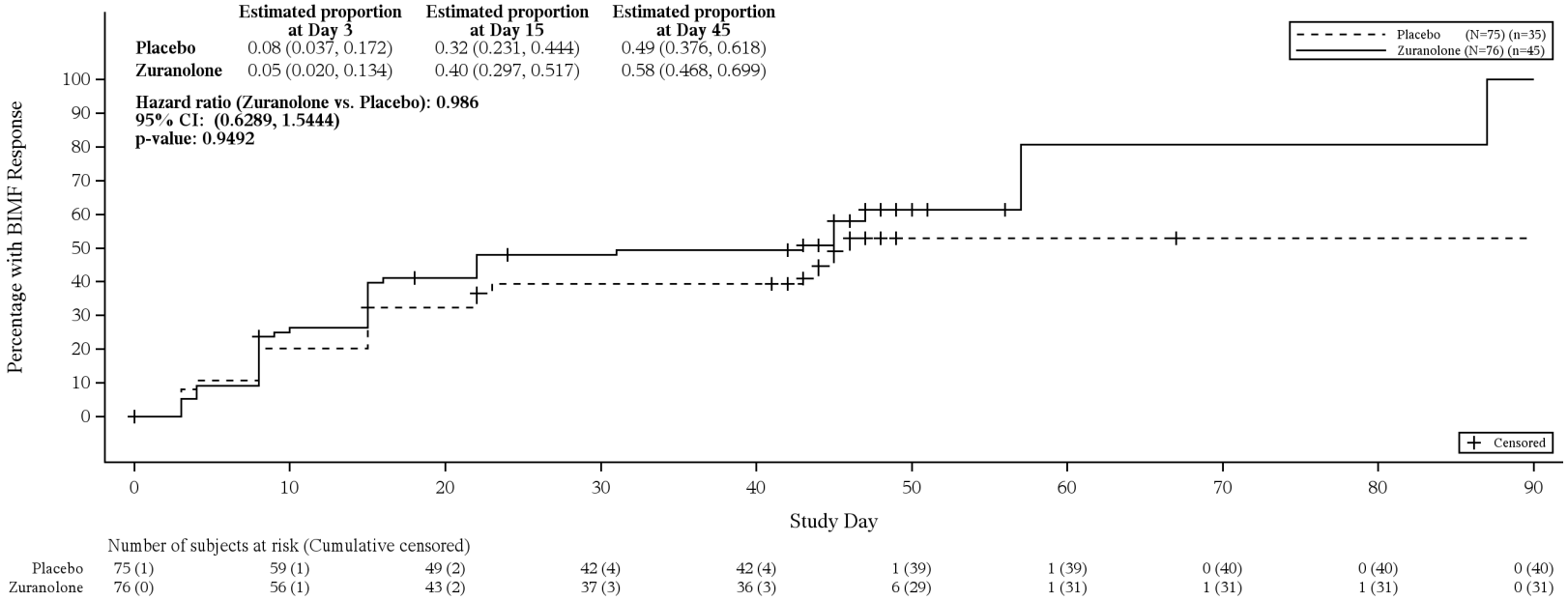
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-201-by.sas:t-bimf-comp-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

3.2.2.2 TTE-Analysen

3.2.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-bimf-comp-resp15-tte-201-ovr.sas:f-bimf-comp-resp15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	35 (46.7)	45 (59.2)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 22.0)	9.0 (8.0 , 15.0)
50th percentile - median (95% CI)	46.0 (23.0, NE)	43.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	57.0 (57.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.986
95% CI for the HR		(0.6289 , 1.5444)
p-value for the HR		0.9492

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-ovr.sas:t-bimf-comp-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.2.2.2 .2 Subgruppen

3.2.2.2 .2 .1 Interaktionstest

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	35 (46.7)	45 (59.2)	
Age Group (years)			
18 - 24, n / N (%)	13/25 (52.0)	10/17 (58.8)	0.1662
25 - 45, n / N (%)	22/50 (44.0)	35/59 (59.3)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	12/22 (54.5)	19/30 (63.3)	0.2407
>=28, n / N (%)	23/53 (43.4)	26/46 (56.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	14/32 (43.8)	14/31 (45.2)	0.0265
White, n / N (%)	19/40 (47.5)	30/44 (68.2)	
Antidepressant Use at Baseline			
Yes, n / N (%)	8/13 (61.5)	10/16 (62.5)	0.8668
No, n / N (%)	27/62 (43.5)	35/60 (58.3)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-int.sas:t-bimf-comp-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	7/21 (33.3)	7/13 (53.8)	0.5715(a)
25-29.9, n / N (%)	11/20 (55.0)	11/21 (52.4)	0.3071(b)
>=30, n / N (%)	17/34 (50.0)	27/42 (64.3)	0.6373(c)
Onset of PPD			
3rd Trimester, n / N (%)	15/32 (46.9)	17/32 (53.1)	0.8913
Postpartum, n / N (%)	20/43 (46.5)	28/44 (63.6)	
Family History of PPD			
Yes, n / N (%)	5/10 (50.0)	4/10 (40.0)	0.9293
No/Unknown, n / N (%)	30/65 (46.2)	41/66 (62.1)	
History of PPD			
1st Episode, n / N (%)	27/59 (45.8)	40/66 (60.6)	0.4008
Recurrent Episode, n / N (%)	8/16 (50.0)	5/10 (50.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	4/8 (50.0)	8/10 (80.0)	NA
>=20, n / N (%)	31/67 (46.3)	37/66 (56.1)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-int.sas:t-bimf-comp-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

3.2.2.2 .2 .2 Subgruppenanalysen

3.2.2.2 .2 .2 .1 Alter

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	13 (52.0)	10 (58.8)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 22.0)	9.0 (3.0 , 22.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	45.0 (8.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.364
95% CI for the HR		(0.1343 , 0.9843)
p-value for the HR		0.0465

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	22 (44.0)	35 (59.3)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 23.0)	10.0 (8.0 , 15.0)
50th percentile - median (95% CI)	46.0 (23.0, NE)	43.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	57.0 (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.179
95% CI for the HR		(0.6873 , 2.0213)
p-value for the HR		0.5504

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

3.2.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	12 (54.5)	19 (63.3)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 23.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	44.0 (15.0, NE)	22.0 (10.0, NE)
75th percentile - Q3 (95% CI)	46.0 (46.0, NE)	47.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.536
95% CI for the HR		(0.2378 , 1.2086)
p-value for the HR		0.1328

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	23 (43.4)	26 (56.5)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 23.0)	15.0 (8.0 , 22.0)
50th percentile - median (95% CI)	NE (23.0, NE)	45.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.168
95% CI for the HR		(0.6616 , 2.0615)
p-value for the HR		0.5925

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

3.2.2.2 .2 .2 .3 Abstammung

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	14 (43.8)	14 (45.2)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 44.0)	43.0 (8.0 , 47.0)
50th percentile - median (95% CI)	45.0 (22.0, NE)	57.0 (45.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (57.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.490
95% CI for the HR		(0.2148 , 1.1155)
p-value for the HR		0.0891

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	19 (47.5)	30 (68.2)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 23.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	46.0 (22.0, NE)	15.0 (15.0 , 22.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (22.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.496
95% CI for the HR		(0.8351 , 2.6782)
p-value for the HR		0.1757

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

3.2.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	8 (61.5)	10 (62.5)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 23.0)	8.0 (3.0 , 15.0)
50th percentile - median (95% CI)	23.0 (4.0, NE)	15.0 (8.0, NE)
75th percentile - Q3 (95% CI)	45.0 (22.0, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.888
95% CI for the HR		(0.3471 , 2.2726)
p-value for the HR		0.8045

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	27 (43.5)	35 (58.3)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 23.0)	15.0 (8.0 , 22.0)
50th percentile - median (95% CI)	NE (43.0, NE)	45.0 (22.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	57.0 (57.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.005
95% CI for the HR		(0.6015 , 1.6778)
p-value for the HR		0.9861

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

3.2.2.2 .2 .2 .5 BMI

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	7 (33.3)	7 (53.8)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	23.0 (4.0, NE)	16.0 (3.0 , 45.0)
50th percentile - median (95% CI)	NE (23.0, NE)	45.0 (8.0, NE)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	NE (31.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.500
95% CI for the HR		(0.5101 , 4.4119)
p-value for the HR		0.4612

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	11 (55.0)	11 (52.4)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	6.0 (3.0 , 15.0)	8.0 (3.0 , 22.0)
50th percentile - median (95% CI)	33.5 (4.0, NE)	45.0 (8.0, NE)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	NE (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.988
95% CI for the HR		(0.4225 , 2.3084)
p-value for the HR		0.9769

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	17 (50.0)	27 (64.3)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 23.0)	15.0 (8.0 , 15.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	22.0 (15.0 , 57.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	57.0 (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.848
95% CI for the HR		(0.4431 , 1.6237)
p-value for the HR		0.6192

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

3.2.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	15 (46.9)	17 (53.1)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 43.0)	15.0 (3.0 , 45.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	45.0 (22.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	57.0 (57.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.902
95% CI for the HR		(0.4298 , 1.8941)
p-value for the HR		0.7858

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	20 (46.5)	28 (63.6)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (4.0 , 23.0)	8.5 (8.0 , 15.0)
50th percentile - median (95% CI)	46.0 (22.0, NE)	16.0 (15.0 , 47.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (31.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.969
95% CI for the HR		(0.5248 , 1.7898)
p-value for the HR		0.9204

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

3.2.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	5 (50.0)	4 (40.0)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0, NE)	15.0 (15.0, NE)
50th percentile - median (95% CI)	NE (3.0, NE)	NE (15.0, NE)
75th percentile - Q3 (95% CI)	NE (23.0, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.941
95% CI for the HR		(0.1794 , 4.9400)
p-value for the HR		0.9431

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	30 (46.2)	41 (62.1)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 22.0)	8.0 (8.0 , 15.0)
50th percentile - median (95% CI)	46.0 (23.0, NE)	31.0 (15.0 , 47.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	57.0 (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.962
95% CI for the HR		(0.5833 , 1.5869)
p-value for the HR		0.8796

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

3.2.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	27 (45.8)	40 (60.6)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 23.0)	8.0 (8.0 , 15.0)
50th percentile - median (95% CI)	NE (23.0, NE)	31.0 (15.0 , 47.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	87.0 (47.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.080
95% CI for the HR		(0.6573 , 1.7730)
p-value for the HR		0.7624

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	8 (50.0)	5 (50.0)
Time to first BIMF Mom's Competency Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 44.0)	15.0 (8.0, NE)
50th percentile - median (95% CI)	45.0 (15.0, NE)	57.0 (8.0, NE)
75th percentile - Q3 (95% CI)	NE (44.0, NE)	57.0 (22.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.562
95% CI for the HR		(0.1511 , 2.0877)
p-value for the HR		0.3891

NOTE 1: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

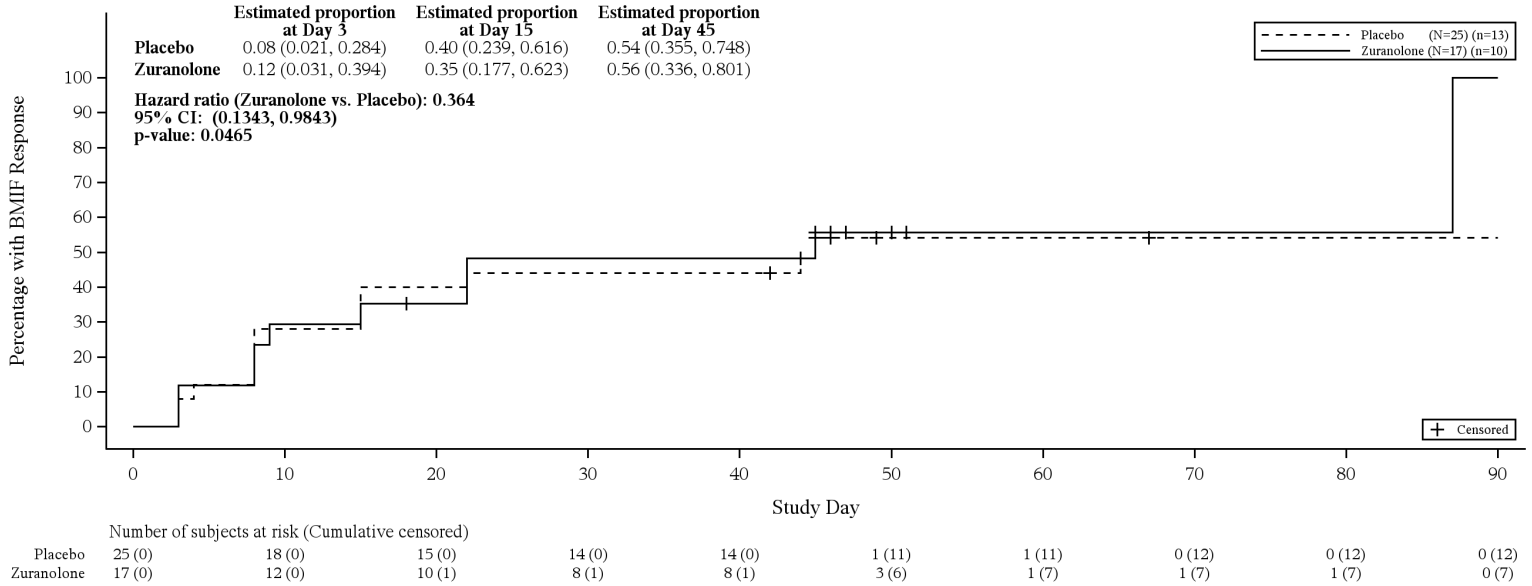
Source: biib125/v_a/germany_amnog/t-bimf-comp-resp15-tte-201-by.sas:t-bimf-comp-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

3.2.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

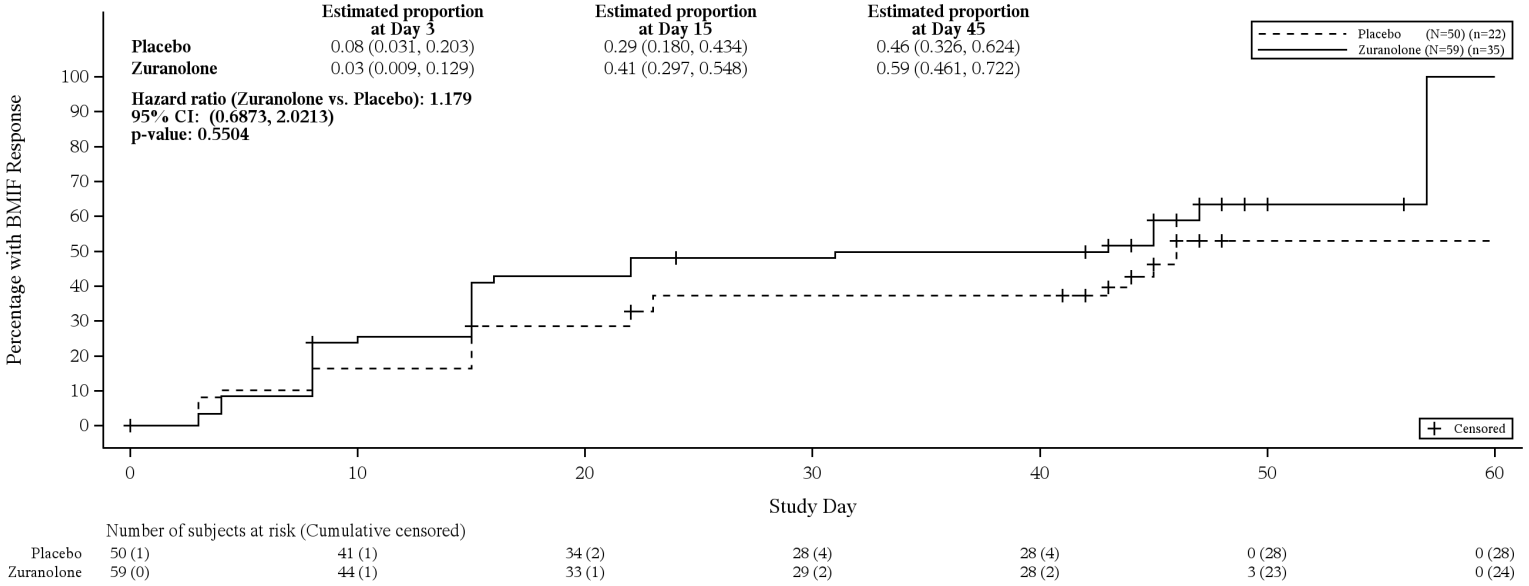
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-comp-resp15-tte-201-by.sas:f-bimf-comp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 25-45



Number of subjects at risk (Cumulative censored)

Placebo	50 (1)	41 (1)	34 (2)	28 (4)	28 (4)	0 (28)	0 (28)
Zuranolone	59 (0)	44 (1)	33 (1)	29 (2)	28 (2)	3 (23)	0 (24)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

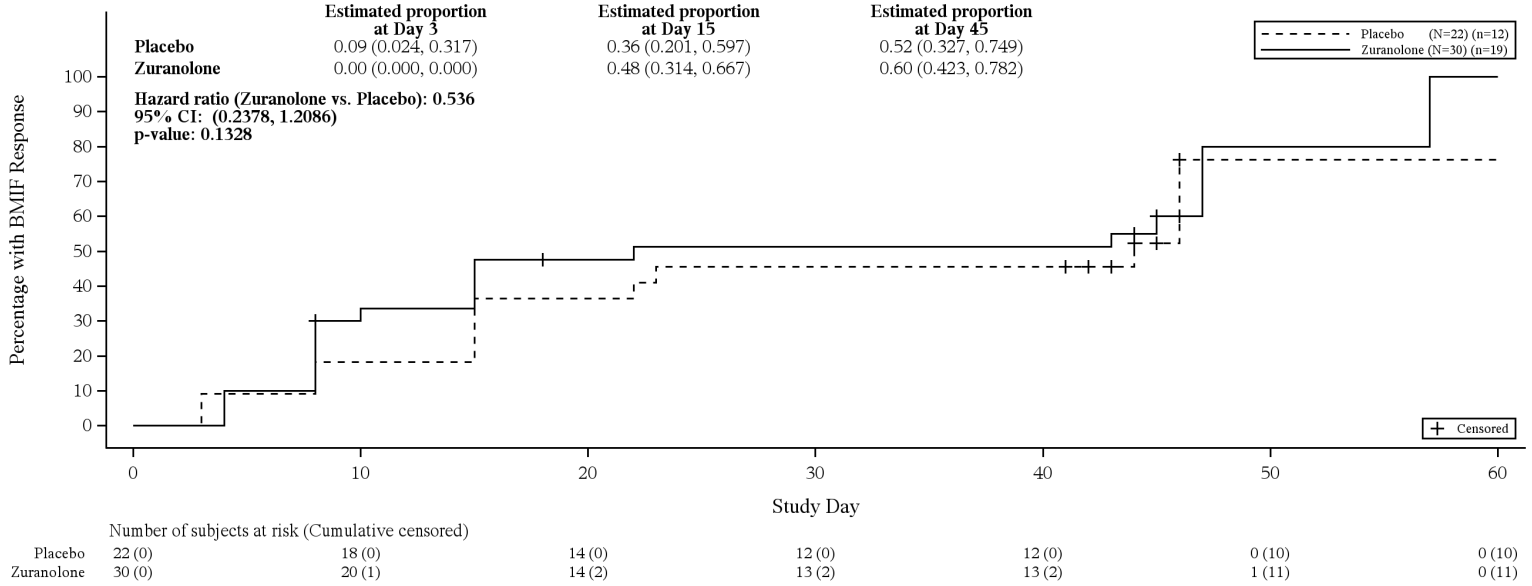
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-comp-resp15-tte-201-by.sas:f-bimf-comp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

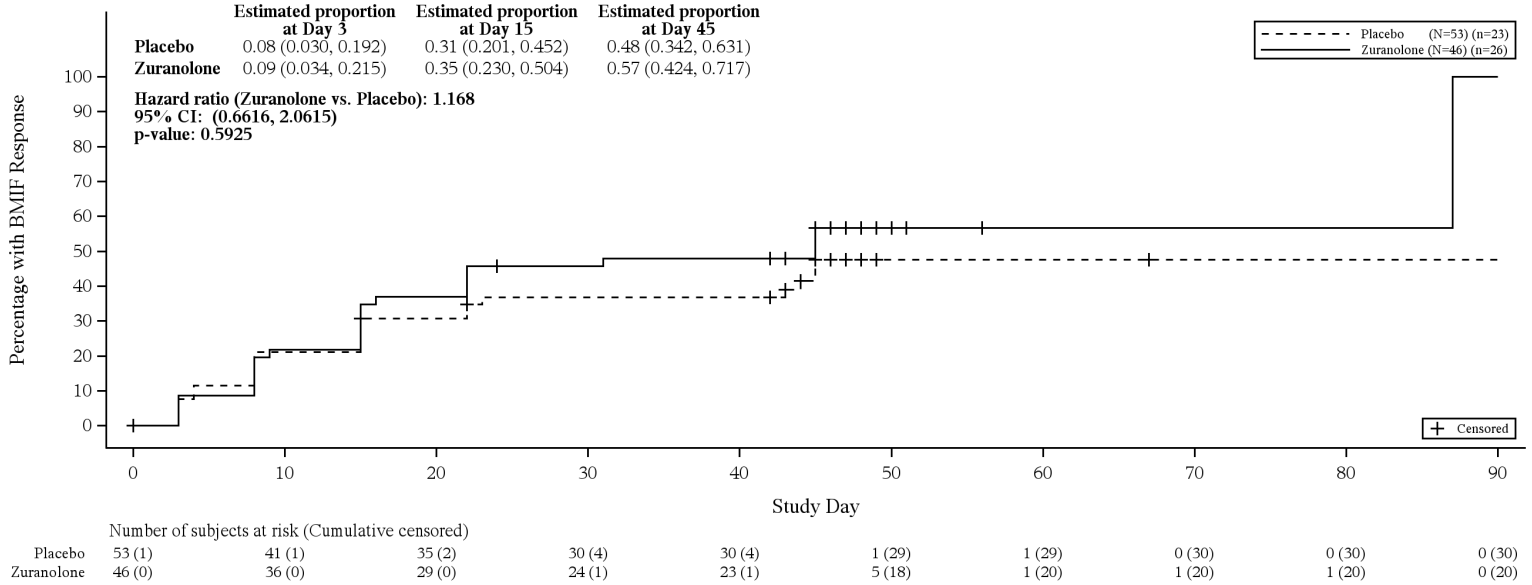
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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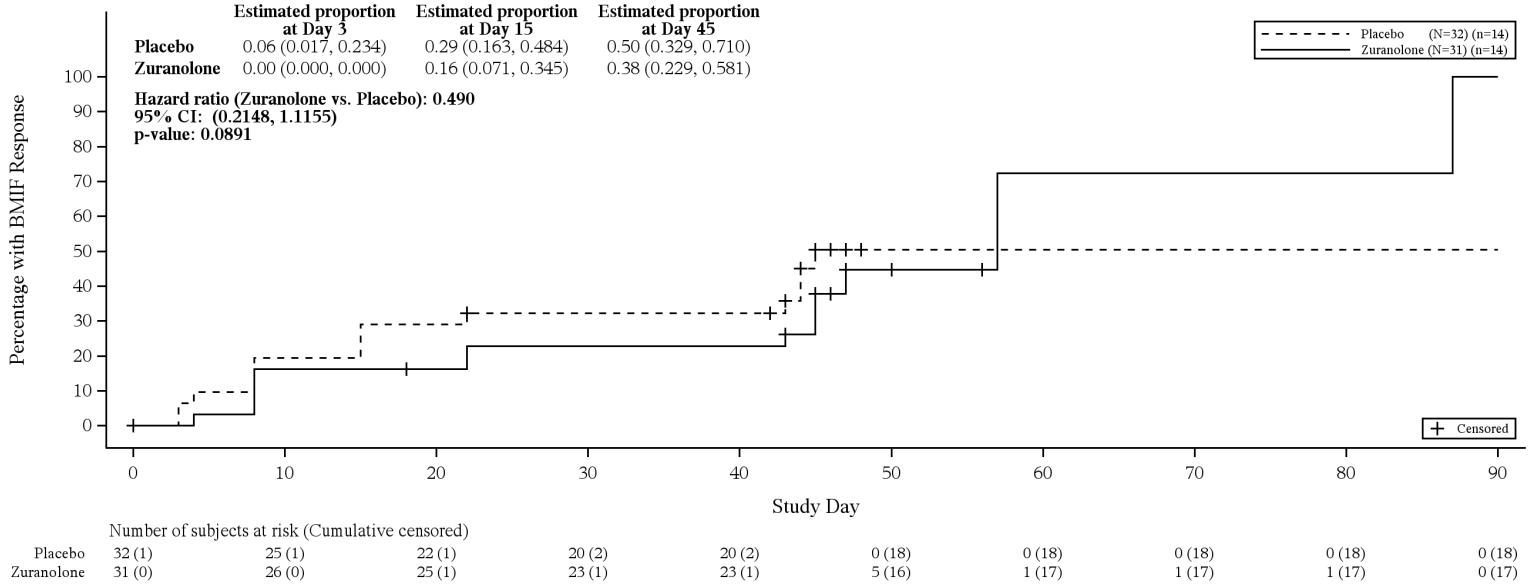
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Number of subjects at risk (Cumulative censored)

Placebo	32 (1)	25 (1)	22 (1)	20 (2)	20 (2)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)
Zuranolone	31 (0)	26 (0)	25 (1)	23 (1)	23 (1)	5 (16)	1 (17)	1 (17)	1 (17)	0 (17)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

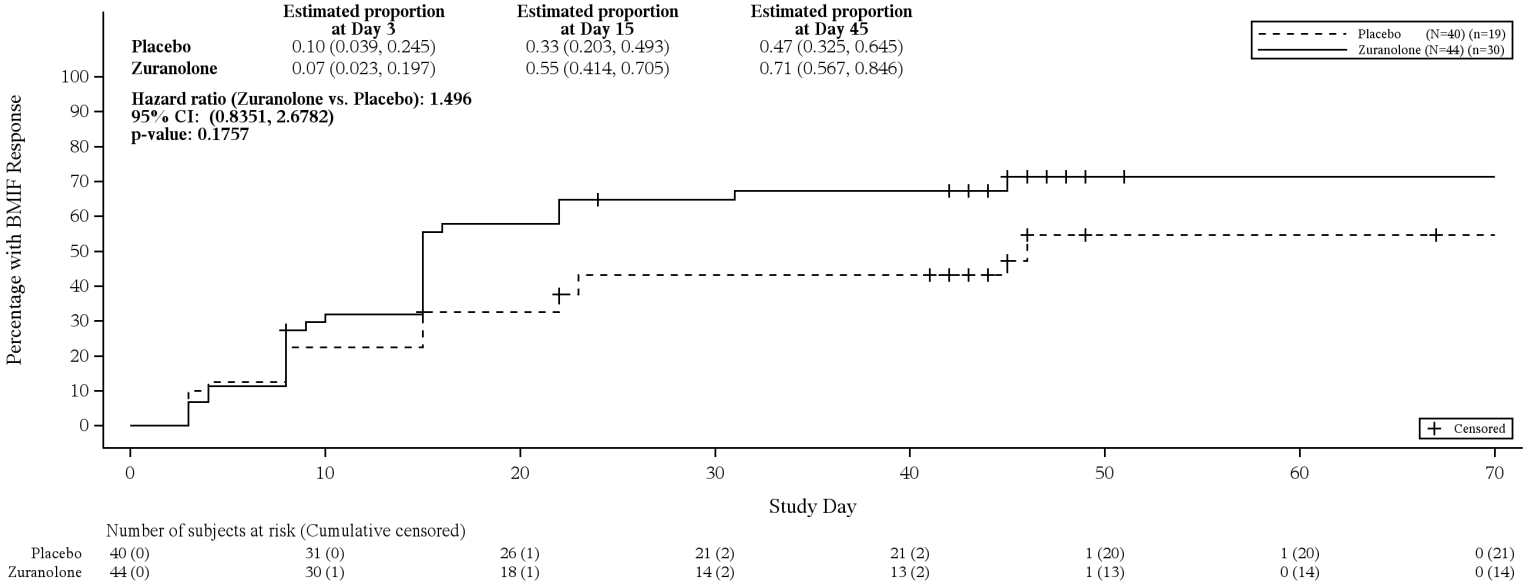
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

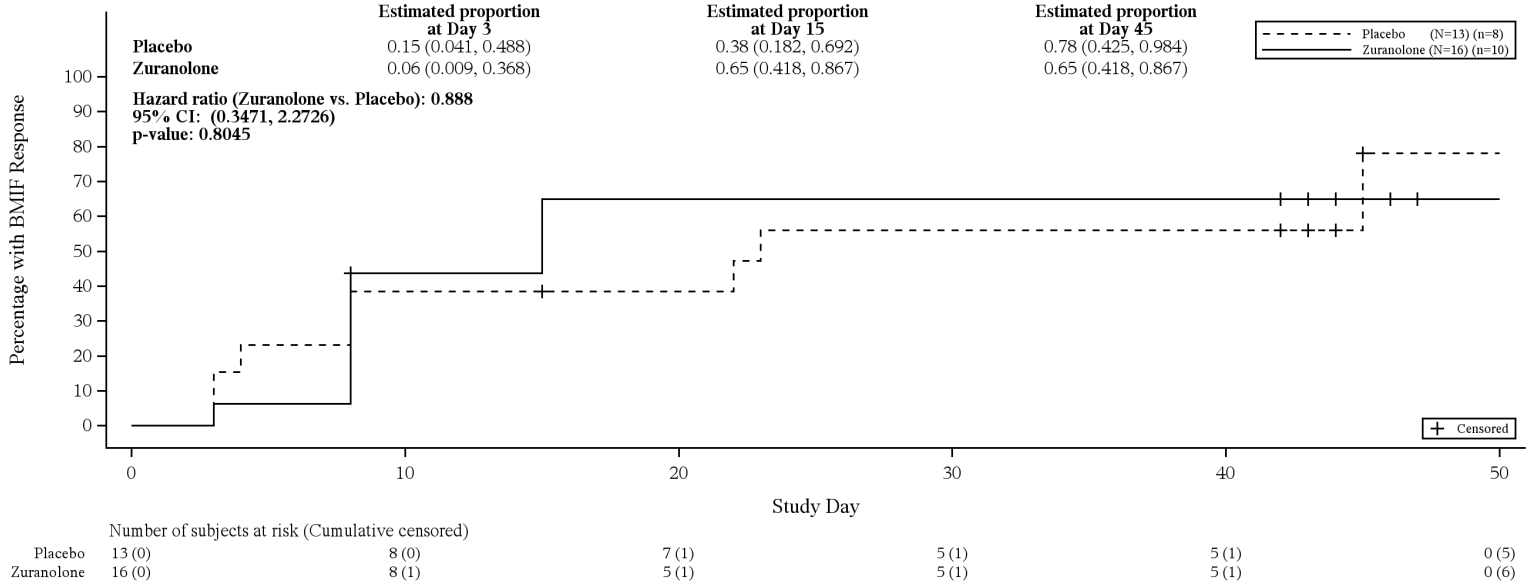
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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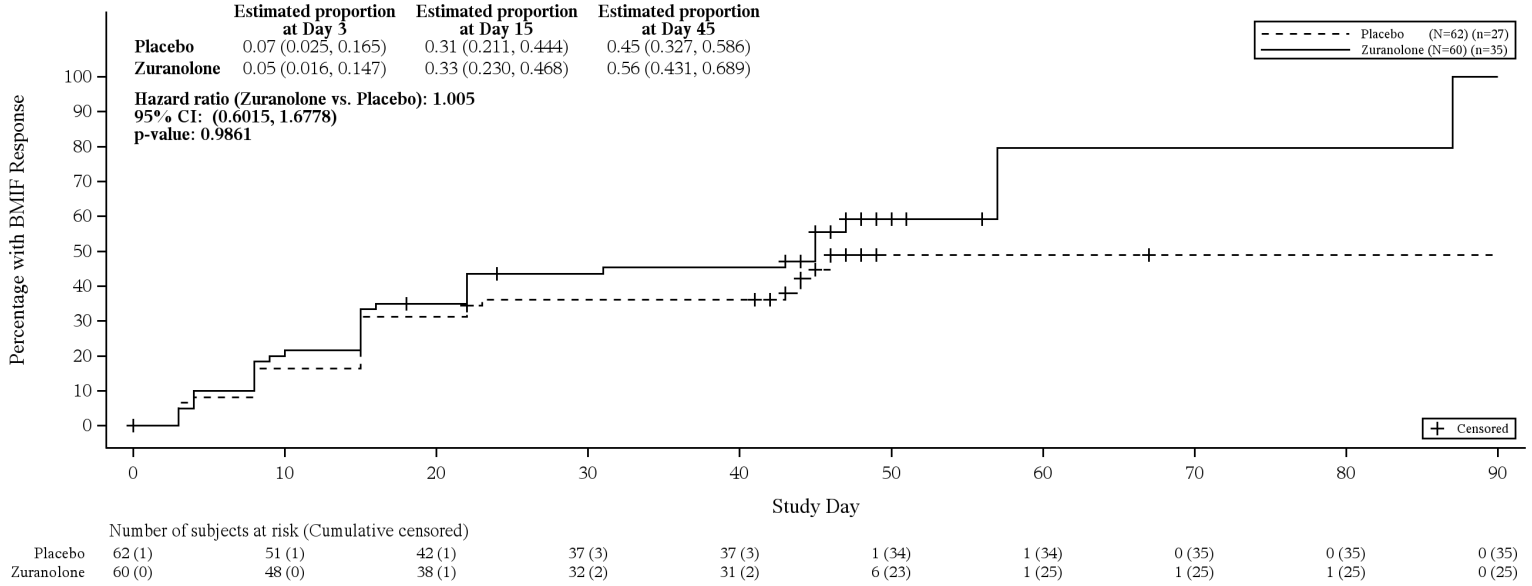
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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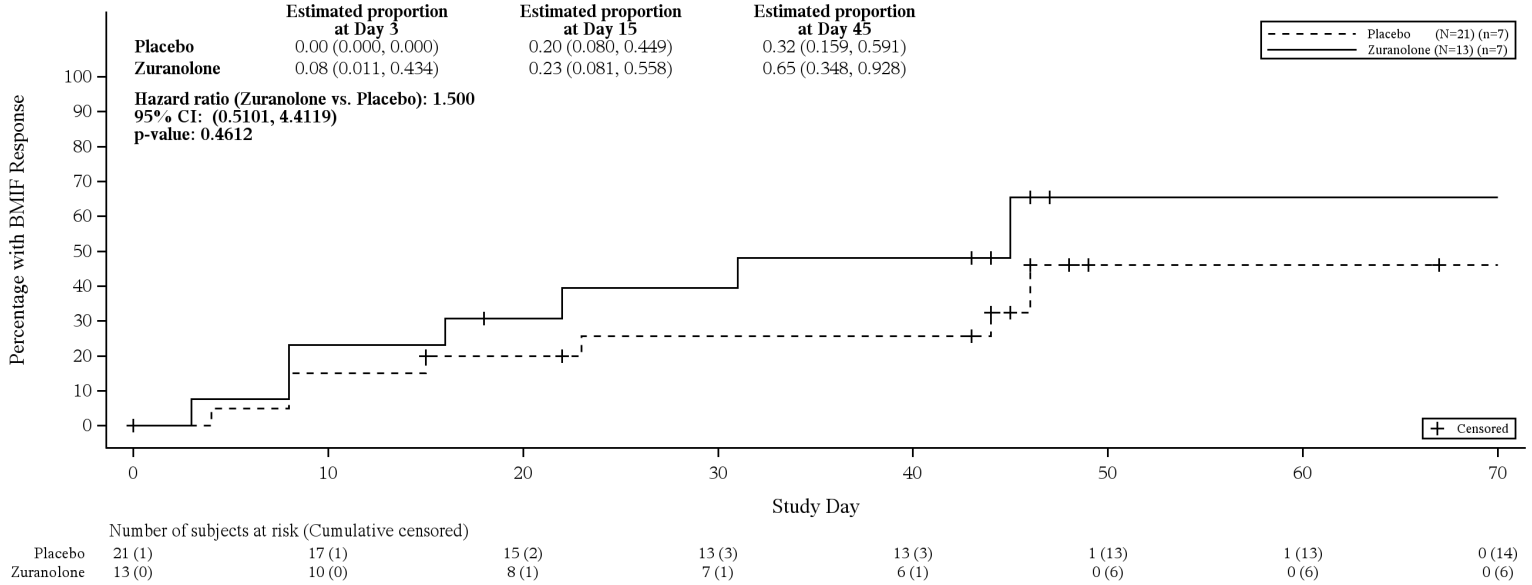
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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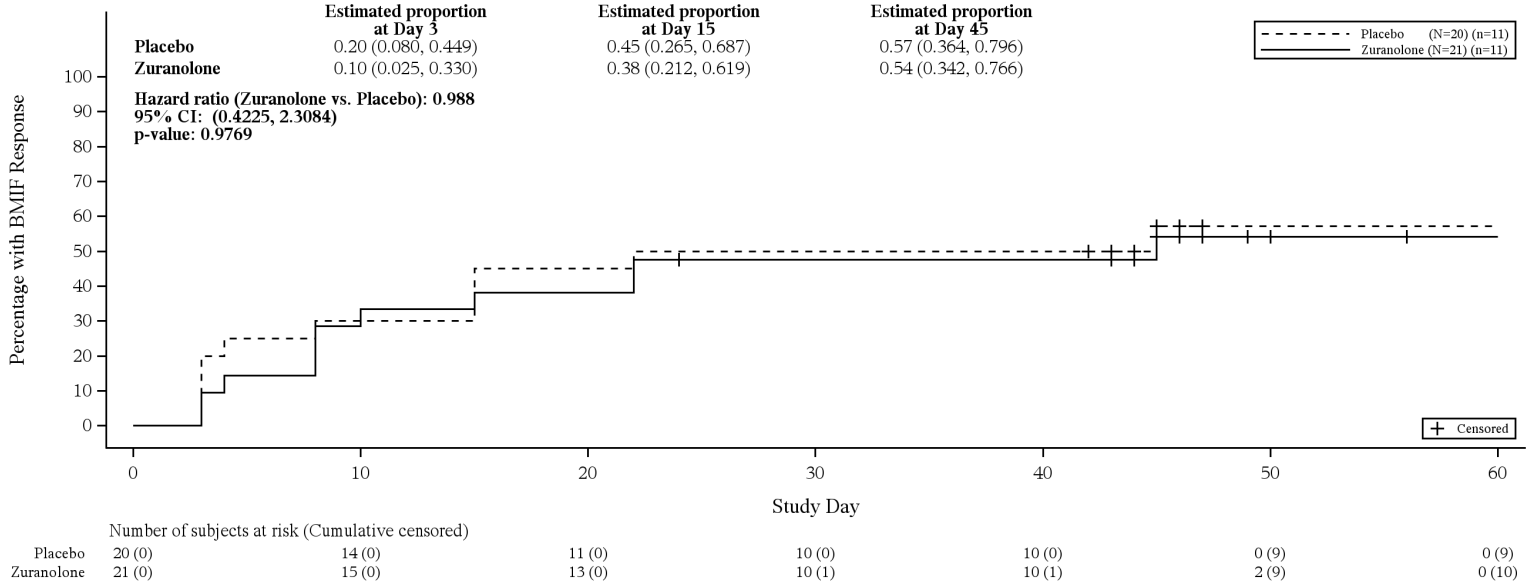
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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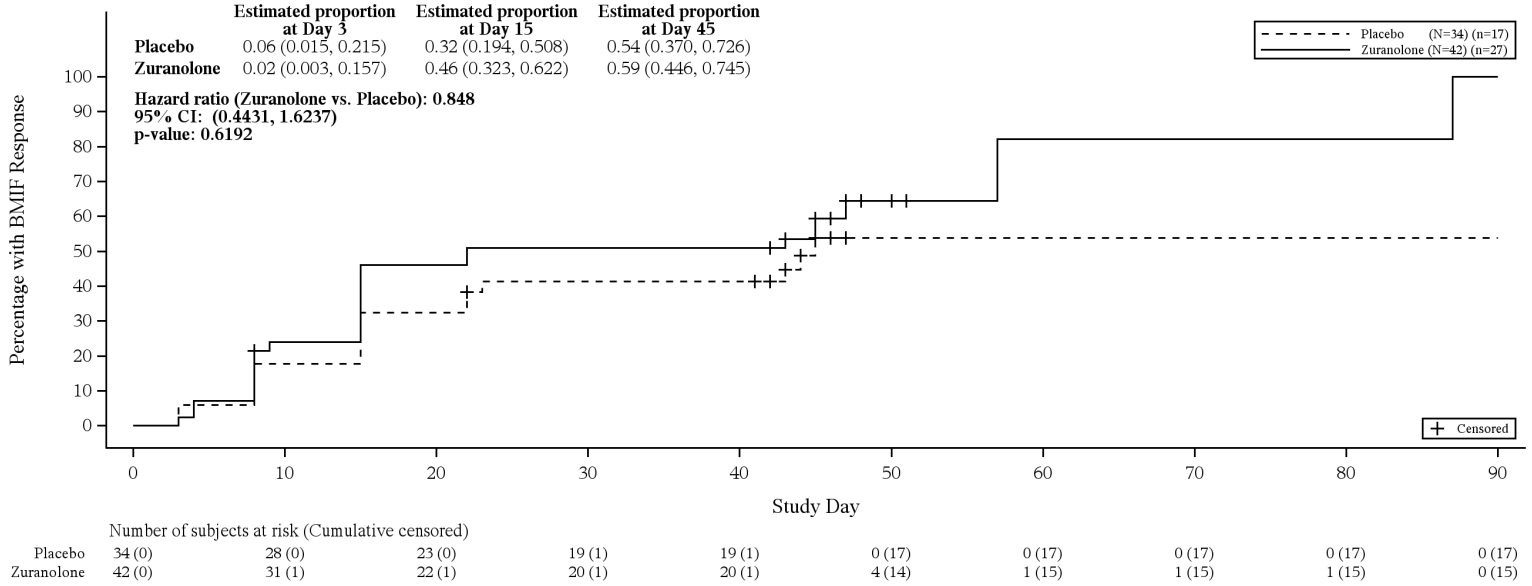
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Number of subjects at risk (Cumulative censored)

Placebo	34 (0)	28 (0)	23 (0)	19 (1)	19 (1)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)
Zuranolone	42 (0)	31 (1)	22 (1)	20 (1)	20 (1)	4 (14)	1 (15)	1 (15)	1 (15)	0 (15)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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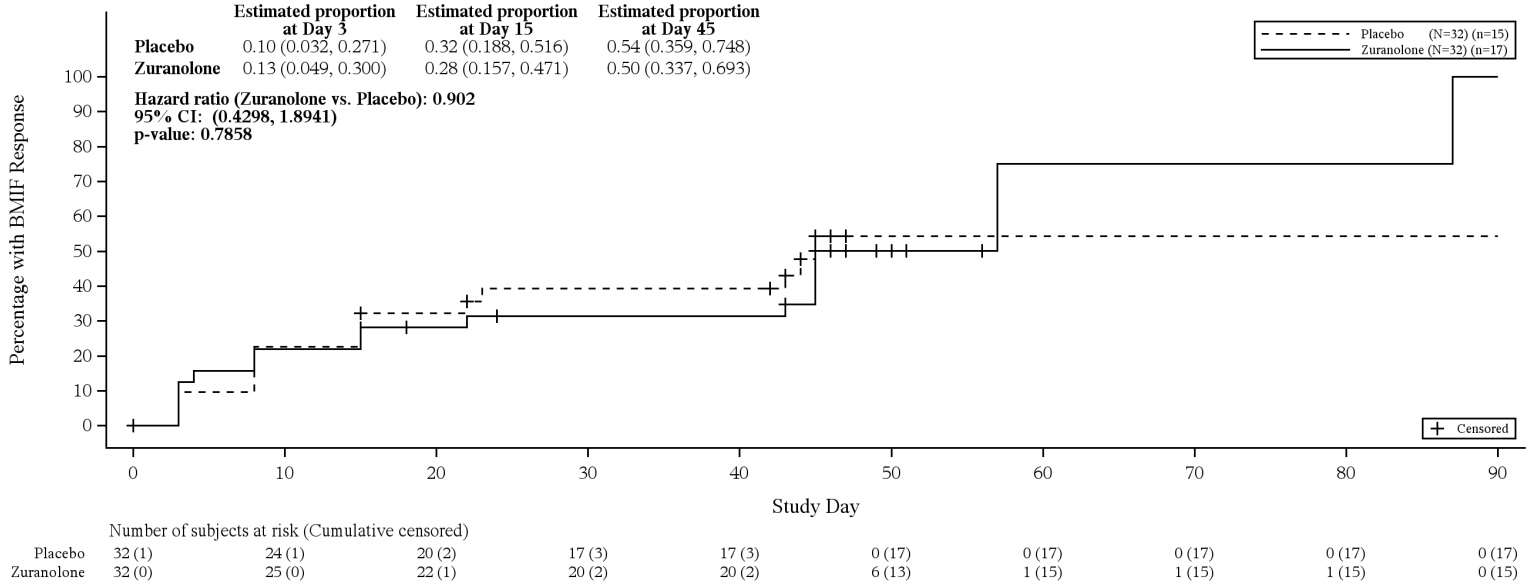
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

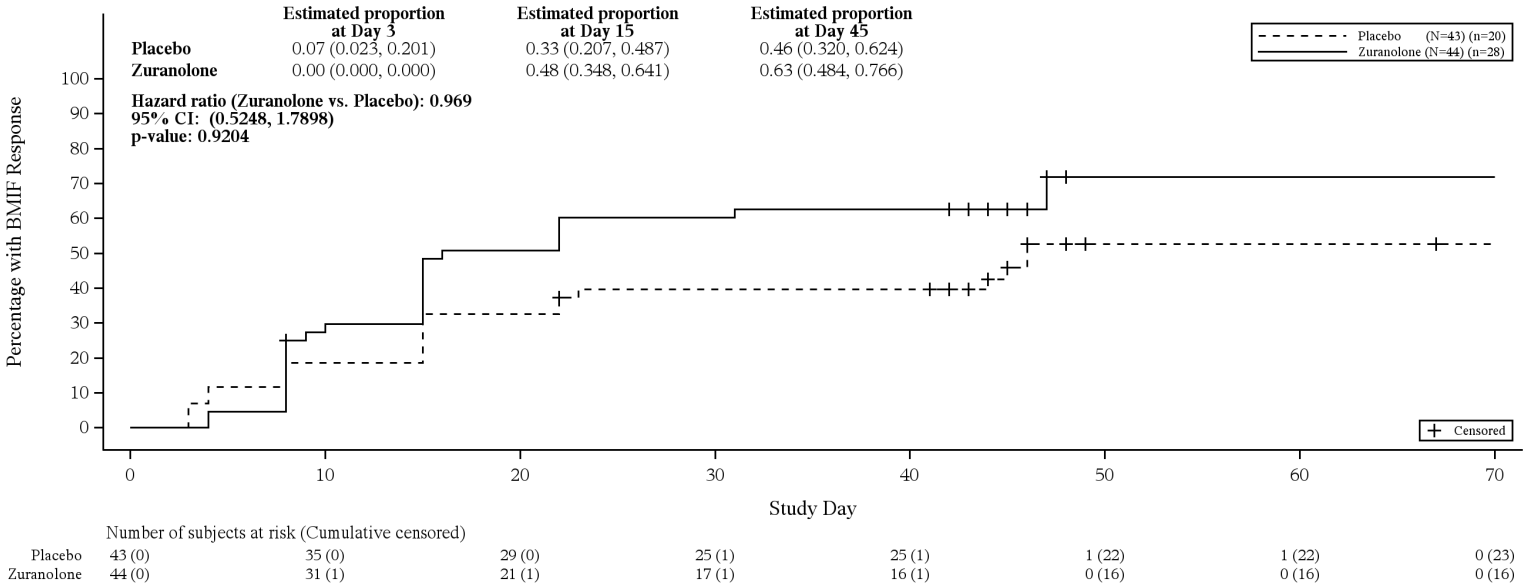
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

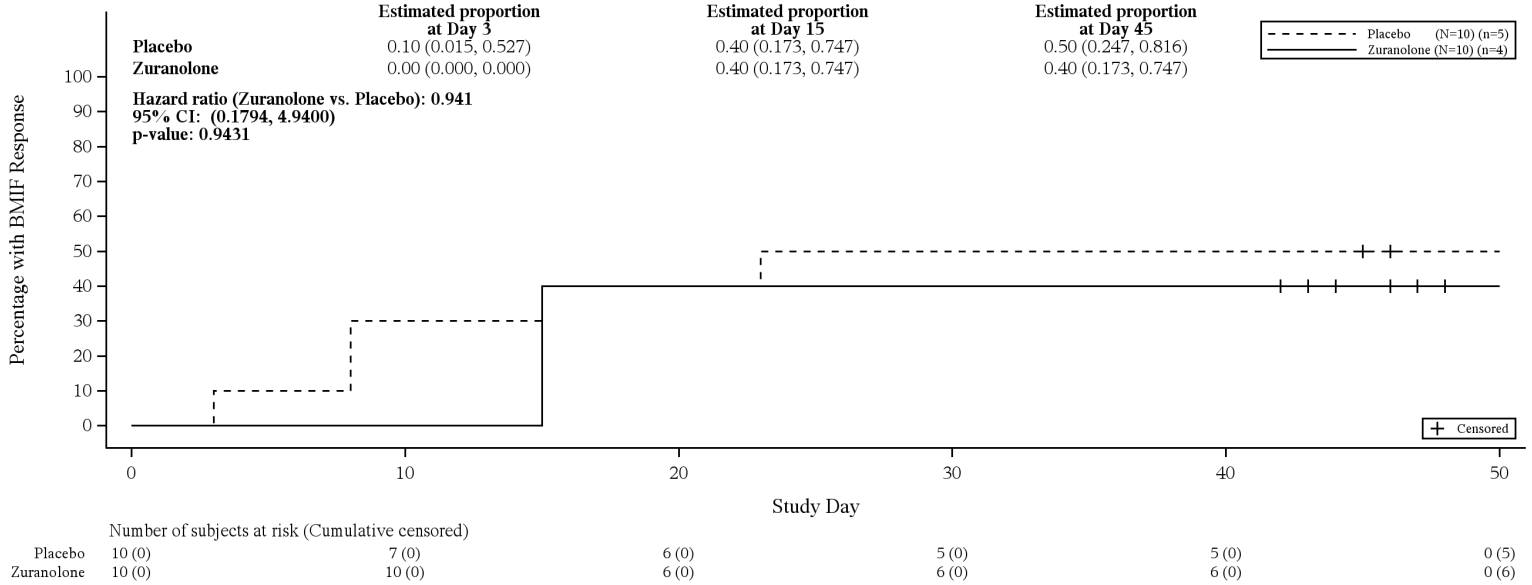
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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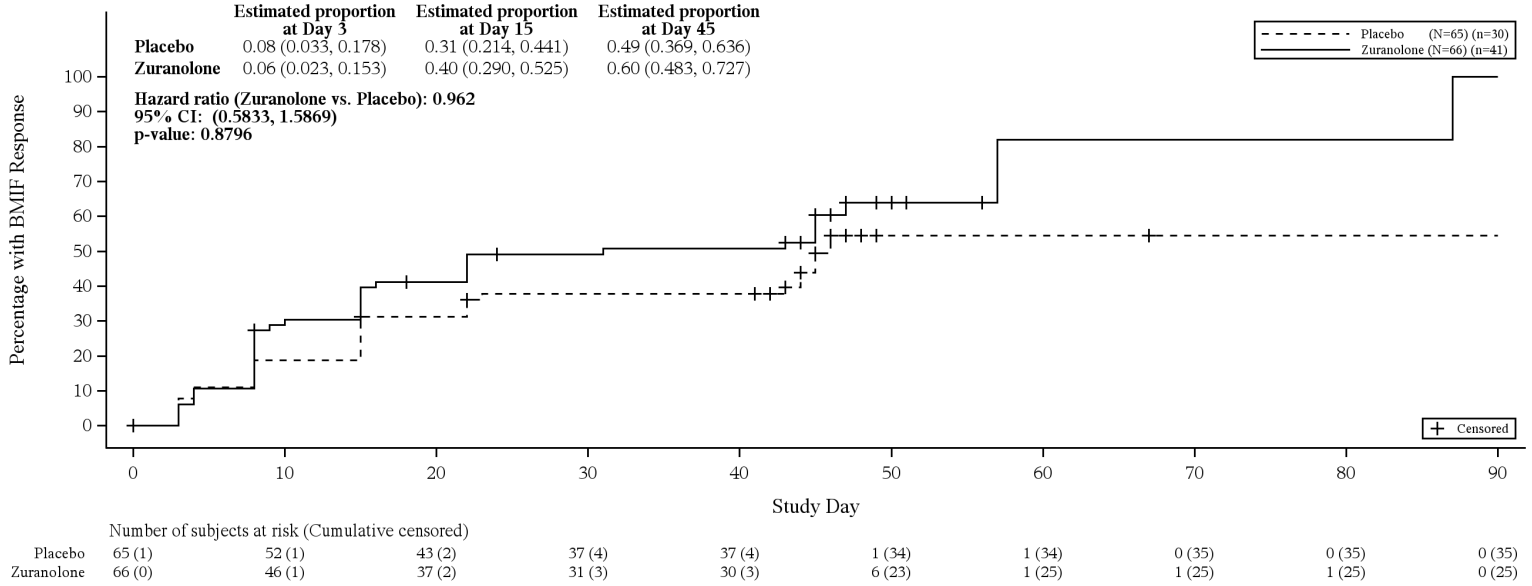
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Number of subjects at risk (Cumulative censored)

Placebo	65 (1)	52 (1)	43 (2)	37 (4)	37 (4)	1 (34)	1 (34)	0 (35)	0 (35)	0 (35)
Zuranolone	66 (0)	46 (1)	37 (2)	31 (3)	30 (3)	6 (23)	1 (25)	1 (25)	1 (25)	0 (25)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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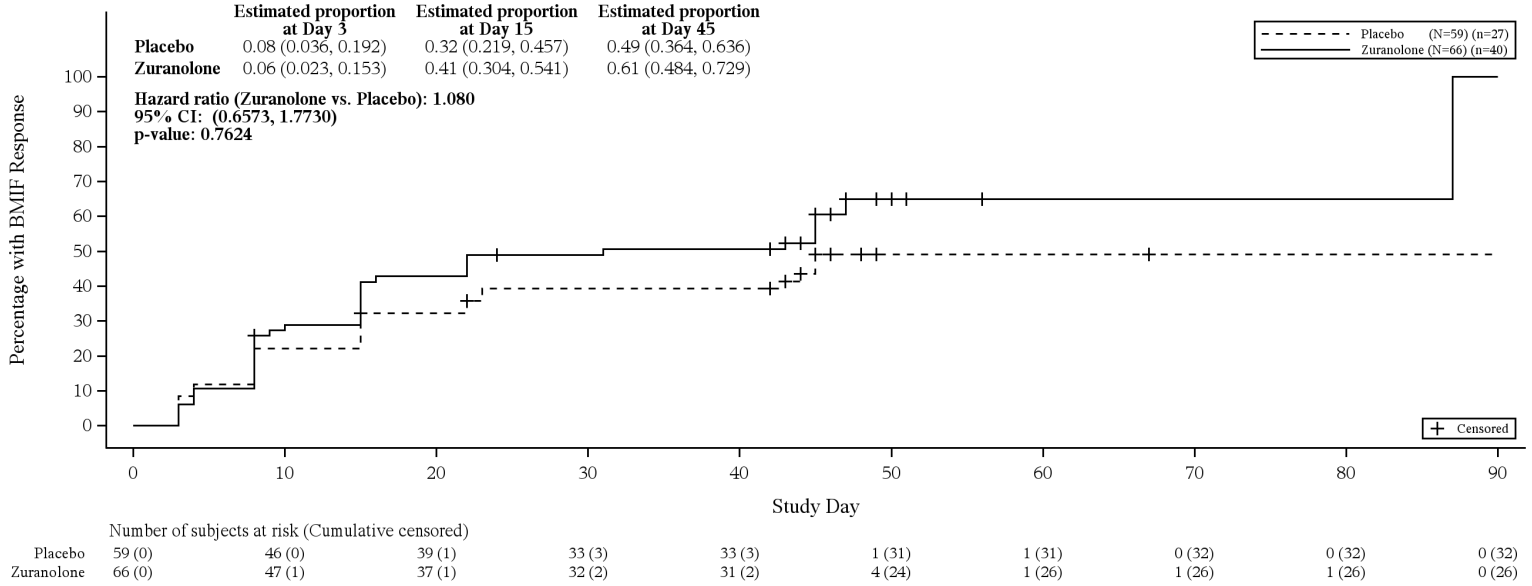
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Number of subjects at risk (Cumulative censored)

Placebo	59 (0)	46 (0)	39 (1)	33 (3)	33 (3)	1 (31)	1 (31)	0 (32)	0 (32)	0 (32)
Zuranolone	66 (0)	47 (1)	37 (1)	32 (2)	31 (2)	4 (24)	1 (26)	1 (26)	1 (26)	0 (26)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

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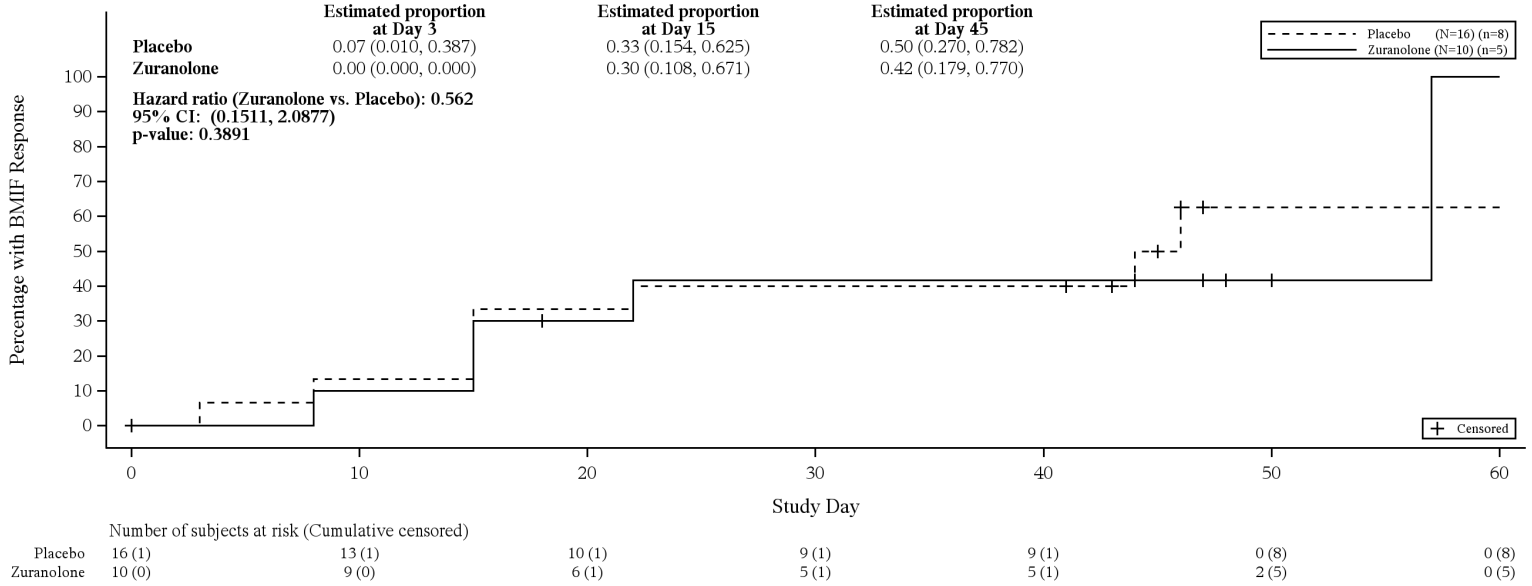
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Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Number of subjects at risk (Cumulative censored)

Placebo	16 (1)	13 (1)	10 (1)	9 (1)	9 (1)	0 (8)	0 (8)
Zuranolone	10 (0)	9 (0)	6 (1)	5 (1)	5 (1)	2 (5)	0 (5)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's competency subscale score response is defined as 9.9 points (15% of total scale range 0-66) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-comp-resp15-tte-201-by.sas:f-bimf-comp-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

3.2.3 Verschlechterung

3.2.3.1 Responder-Analysen

3.2.3.1 .1 ITT-Population

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with worsening, n (%) [2]	1 (1.3)	0
Number of subjects with missing evaluation, n (%)	3 (4.0)	4 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.014, 7.950)
p-value for RR		0.4939
OR - Odds Ratio (Zuranolone vs. Placebo)		0.32
95% CI for the OR		(0.013, 8.096)
p-value for OR		0.4930
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.049, 0.023)
p-value for ARR		0.4715

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's competency subscale score worsening (9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-201-ovr.sas:t-bimf-comp-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with worsening, n (%) [2]	1 (1.3)	1 (1.3)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.99
95% CI for the RR		(0.063, 15.489)
p-value for RR		0.9925
OR - Odds Ratio (Zuranolone vs. Placebo)		0.99
95% CI for the OR		(0.061, 16.070)
p-value for OR		0.9925
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.037, 0.036)
p-value for ARR		0.9925

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's competency subscale score worsening (9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-201-ovr.sas:t-bimf-comp-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 3 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with worsening, n (%) [2]	1 (1.3)	1 (1.3)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.99
95% CI for the RR		(0.063, 15.489)
p-value for RR		0.9925
OR - Odds Ratio (Zuranolone vs. Placebo)		0.99
95% CI for the OR		(0.061, 16.070)
p-value for OR		0.9925
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.037, 0.036)
p-value for ARR		0.9925

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score worsening (9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-201-ovr.sas:t-bimf-comp-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with worsening, n (%) [2]	1 (1.3)	2 (2.6)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.97
95% CI for the RR		(0.183, 21.308)
p-value for RR		0.5754
OR - Odds Ratio (Zuranolone vs. Placebo)		2.00
95% CI for the OR		(0.177, 22.536)
p-value for OR		0.5749
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.031, 0.057)
p-value for ARR		0.5663

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's competency subscale score worsening (9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-201-ovr.sas:t-bimf-comp-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	1 (1.3)	2 (2.6)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.97
95% CI for the RR		(0.183, 21.308)
p-value for RR		0.5754
OR - Odds Ratio (Zuranolone vs. Placebo)		2.00
95% CI for the OR		(0.177, 22.536)
p-value for OR		0.5749
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.031, 0.057)
p-value for ARR		0.5663

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's competency subscale score worsening (9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-201-ovr.sas:t-bimf-comp-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.2.3.1 .2 Subgruppen

3.2.3.1 .2 .1 Interaktionstest

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	1 (1.3)	1 (1.3)	
Number of subjects with response at Day 45, n (%)	1 (1.3)	2 (2.6)	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	0/25	0/17	
25 - 45, n / N (%)	1/50 (2.0)	1/59 (1.7)	
Day 45			
18 - 24, n / N (%)	1/25 (4.0)	1/17 (5.9)	
25 - 45, n / N (%)	0/50	1/59 (1.7)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score worsening is defined as 9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-201-int.sas:t-bimf-comp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	0/22	1/30 (3.3)	
>=28, n / N (%)	1/53 (1.9)	0/46	
Day 45			
<28, n / N (%)	1/22 (4.5)	0/30	
>=28, n / N (%)	0/53	2/46 (4.3)	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	1/32 (3.1)	0/31	
White, n / N (%)	0/40	1/44 (2.3)	
Day 45			
Black or African American, n / N (%)	1/32 (3.1)	2/31 (6.5)	
White, n / N (%)	0/40	0/44	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score worsening is defined as 9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-201-int.sas:t-bimf-comp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	1/62 (1.6)	1/60 (1.7)	
Day 45			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	1/62 (1.6)	2/60 (3.3)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score worsening is defined as 9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-201-int.sas:t-bimf-comp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	0/21	0/13	
25-29.9, n / N (%)	0/20	0/21	
>=30, n / N (%)	1/34 (2.9)	1/42 (2.4)	
Day 45			
<=24.9, n / N (%)	0/21	1/13 (7.7)	
25-29.9, n / N (%)	0/20	0/21	
>=30, n / N (%)	1/34 (2.9)	1/42 (2.4)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score worsening is defined as 9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-201-int.sas:t-bimf-comp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	0/32	0/32	
Postpartum, n / N (%)	1/43 (2.3)	1/44 (2.3)	
Day 45			
3rd Trimester, n / N (%)	0/32	1/32 (3.1)	
Postpartum, n / N (%)	1/43 (2.3)	1/44 (2.3)	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/10	1/10 (10.0)	
No/Unknown, n / N (%)	1/65 (1.5)	0/66	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	1/65 (1.5)	2/66 (3.0)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score worsening is defined as 9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-201-int.sas:t-bimf-comp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	0/59	1/66 (1.5)	
Recurrent Episode, n / N (%)	1/16 (6.3)	0/10	
Day 45			
1st Episode, n / N (%)	1/59 (1.7)	2/66 (3.0)	
Recurrent Episode, n / N (%)	0/16	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	1/67 (1.5)	1/66 (1.5)	
Day 45			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	1/67 (1.5)	2/66 (3.0)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score worsening is defined as 9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-201-int.sas:t-bimf-comp-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

3.2.3.1 .2 .2 Subgruppenanalysen

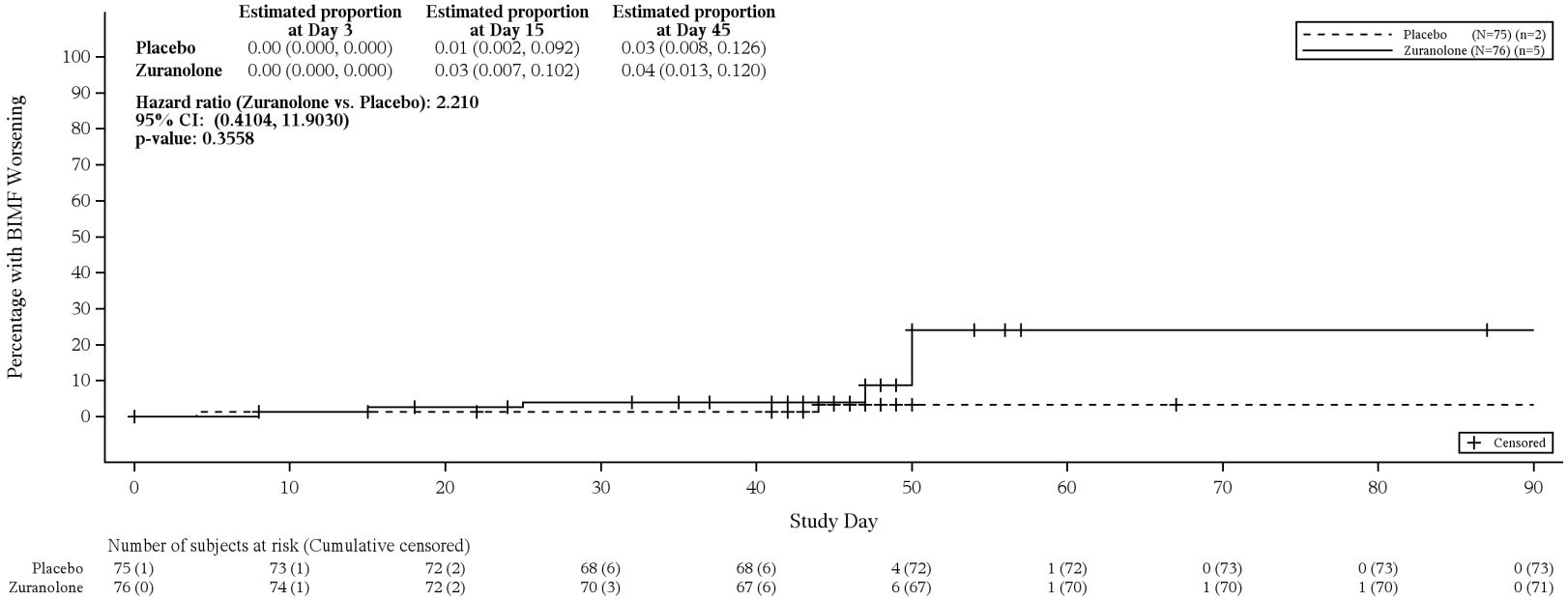
Nicht zutreffend.

3.2.3.2 TTE-Analysen

3.2.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing BIMF Mom's competency subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: BIMF Mom's competency subscale score worsening is defined as 9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-bimf-comp-wors15-tte-201-ovr.sas:f-bimf-comp-wors15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	2 (2.7)	5 (6.6)
Time to first BIMF Mom's Competency Subscale worsening (days) [3]		
25th percentile - Q1 (95% CI)	NE (NE, NE)	NE (47.0, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (50.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.210
95% CI for the HR		(0.4104 , 11.9030)
p-value for the HR		0.3558

NOTE 1: BIMF Mom's competency subscale score worsening is defined as 9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's competency subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's competency subscale score worsening. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's competency subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-tte-201-ovr.sas:t-bimf-comp-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.2.3.2 .2 Subgruppen

3.2.3.2 .2 .1 Interaktionstest

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	2 (2.7)	5 (6.6)	
Age Group (years)			
18 - 24, n / N (%)	1/25 (4.0)	3/17 (17.6)	NA
25 - 45, n / N (%)	1/50 (2.0)	2/59 (3.4)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	1/22 (4.5)	2/30 (6.7)	NA
>=28, n / N (%)	1/53 (1.9)	3/46 (6.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	2/32 (6.3)	3/31 (9.7)	NA
White, n / N (%)	0/40	2/44 (4.5)	
Antidepressant Use at Baseline			
Yes, n / N (%)	0/13	0/16	NA
No, n / N (%)	2/62 (3.2)	5/60 (8.3)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score worsening is defined as 9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-tte-201-int.sas:t-bimf-comp-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Competency Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	0/21	1/13 (7.7)	NA(a)
25-29.9, n / N (%)	0/20	0/21	NA(b)
>=30, n / N (%)	2/34 (5.9)	4/42 (9.5)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	0/32	3/32 (9.4)	NA
Postpartum, n / N (%)	2/43 (4.7)	2/44 (4.5)	
Family History of PPD			
Yes, n / N (%)	0/10	1/10 (10.0)	NA
No/Unknown, n / N (%)	2/65 (3.1)	4/66 (6.1)	
History of PPD			
1st Episode, n / N (%)	1/59 (1.7)	5/66 (7.6)	NA
Recurrent Episode, n / N (%)	1/16 (6.3)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/8	0/10	NA
>=20, n / N (%)	2/67 (3.0)	5/66 (7.6)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's competency subscale score worsening is defined as 9.9 points (15% of total scale range 0-66) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-comp-wors15-tte-201-int.sas:t-bimf-comp-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

3.2.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

3.2.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

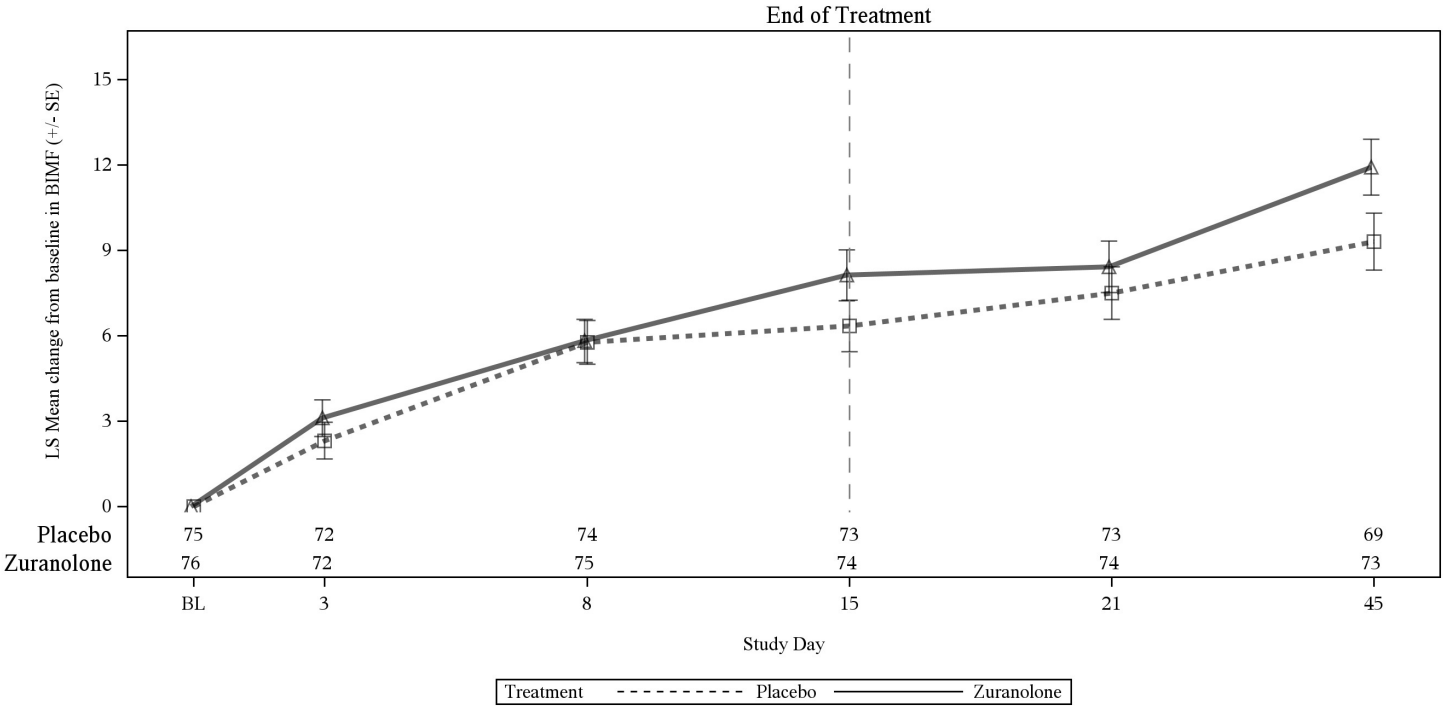
3.3 BIMF Bedürfnisse

3.3.1 MMRM

3.3.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/f-bimf-need-mmrm-201-ovr.sas:f-bimf-need-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 3		
n	72	72
LS Mean (SE)	2.32 (0.650)	3.11 (0.647)
95% CI for the LS Mean	1.03, 3.60	1.83, 4.39
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.80 (0.917)
95% CI for the LS Mean		-1.02, 2.61
p-value		0.3870
Hedges' g (Zuranolone vs. Placebo)		0.144
95% CI for Hedges' g		-0.1832, 0.4710
Day 8		
n	74	75
LS Mean (SE)	5.77 (0.761)	5.82 (0.754)
95% CI for the LS Mean	4.26, 7.27	4.33, 7.31
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.05 (1.071)
95% CI for the LS Mean		-2.06, 2.17
p-value		0.9597
Hedges' g (Zuranolone vs. Placebo)		0.008
95% CI for Hedges' g		-0.3129, 0.3294

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-ovr.sas:t-bimf-need-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	6.35 (0.902)	8.13 (0.893)
95% CI for the LS Mean	4.57, 8.13	6.36, 9.89
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.78 (1.270)
95% CI for the LS Mean		-0.73, 4.29
p-value		0.1636
Hedges' g (Zuranolone vs. Placebo)		0.230
95% CI for Hedges' g		-0.0946, 0.5542
Day 21		
n	73	74
LS Mean (SE)	7.50 (0.916)	8.43 (0.907)
95% CI for the LS Mean	5.69, 9.31	6.64, 10.22
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.93 (1.289)
95% CI for the LS Mean		-1.62, 3.48
p-value		0.4712
Hedges' g (Zuranolone vs. Placebo)		0.119
95% CI for Hedges' g		-0.2051, 0.4422

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-ovr.sas:t-bimf-need-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score: 217-PPD-201B - ITT population

Page: 3 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 45		
n	69	73
LS Mean (SE)	9.31 (1.001)	11.92 (0.982)
95% CI for the LS Mean	7.33, 11.29	9.97, 13.86
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.61 (1.403)
95% CI for the LS Mean		-0.16, 5.38
p-value		0.0650
Hedges' g (Zuranolone vs. Placebo)		0.311
95% CI for Hedges' g		-0.0204, 0.6417

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-ovr.sas:t-bimf-need-mmrm-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.3.1.2 Subgruppen

3.3.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.8248
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.5627
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.5816
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.8885
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup interaction analysis.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-int.sas:t-bimf-need-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.3410(a)
25-29.9	20	21	0.6715(b)
>=30	34	42	0.1052(c)
Onset of PPD			
3rd Trimester	32	32	0.9287
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.3334
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.1991
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup interaction analysis.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-int.sas:t-bimf-need-mmrm-201-int-itta.rtf **Run Date:** 24SEP2025

3.3.1.2 .2 Subgruppenanalysen

3.3.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Age Group: 217-PPD-201B - ITT population

Page: 1 of 6

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 3		
n	25	16
LS Mean (SE)	2.72 (0.986)	1.61 (1.218)
95% CI for the LS Mean	0.72, 4.71	-0.86, 4.07
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.11 (1.576)
95% CI for the LS Mean		-4.30, 2.08
p-value		0.4859
Hedges' g (Zuranolone vs. Placebo)		-0.221
95% CI for Hedges' g		-0.8503, 0.4084
Day 8		
n	25	17
LS Mean (SE)	4.76 (1.250)	5.76 (1.522)
95% CI for the LS Mean	2.23, 7.28	2.69, 8.84
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.01 (1.979)
95% CI for the LS Mean		-2.99, 5.01
p-value		0.6132
Hedges' g (Zuranolone vs. Placebo)		0.157
95% CI for Hedges' g		-0.4599, 0.7742

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	5.92 (1.547)	8.47 (1.881)
95% CI for the LS Mean	2.79, 9.04	4.67, 12.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.55 (2.443)
95% CI for the LS Mean		-2.38, 7.49
p-value		0.3021
Hedges' g (Zuranolone vs. Placebo)		0.322
95% CI for Hedges' g		-0.2976, 0.9424
Day 21		
n	25	16
LS Mean (SE)	7.36 (1.576)	10.75 (1.938)
95% CI for the LS Mean	4.17, 10.54	6.84, 14.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.40 (2.505)
95% CI for the LS Mean		-1.67, 8.46
p-value		0.1826
Hedges' g (Zuranolone vs. Placebo)		0.426
95% CI for Hedges' g		-0.2083, 1.0601

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 45		
n	25	16
LS Mean (SE)	9.44 (1.594)	13.09 (1.978)
95% CI for the LS Mean	6.20, 12.67	9.08, 17.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.65 (2.546)
95% CI for the LS Mean		-1.51, 8.81
p-value		0.1601
Hedges' g (Zuranolone vs. Placebo)		0.450
95% CI for Hedges' g		-0.1850, 1.0851

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 3		
n	47	56
LS Mean (SE)	2.01 (0.837)	3.61 (0.766)
95% CI for the LS Mean	0.35, 3.67	2.09, 5.13
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.60 (1.136)
95% CI for the LS Mean		-0.65, 3.86
p-value		0.1617
Hedges' g (Zuranolone vs. Placebo)		0.277
95% CI for Hedges' g		-0.1127, 0.6664
Day 8		
n	49	58
LS Mean (SE)	6.20 (0.964)	5.92 (0.883)
95% CI for the LS Mean	4.29, 8.11	4.17, 7.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.28 (1.309)
95% CI for the LS Mean		-2.87, 2.32
p-value		0.8319
Hedges' g (Zuranolone vs. Placebo)		-0.041
95% CI for Hedges' g		-0.4213, 0.3393

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	6.49 (1.124)	8.12 (1.028)
95% CI for the LS Mean	4.27, 8.72	6.08, 10.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.62 (1.524)
95% CI for the LS Mean		-1.40, 4.65
p-value		0.2889
Hedges' g (Zuranolone vs. Placebo)		0.207
95% CI for Hedges' g		-0.1777, 0.5923
Day 21		
n	48	58
LS Mean (SE)	7.49 (1.127)	7.87 (1.028)
95% CI for the LS Mean	5.26, 9.73	5.83, 9.91
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.38 (1.527)
95% CI for the LS Mean		-2.65, 3.40
p-value		0.8062
Hedges' g (Zuranolone vs. Placebo)		0.048
95% CI for Hedges' g		-0.3349, 0.4301

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 45		
n	44	57
LS Mean (SE)	9.17 (1.285)	11.68 (1.153)
95% CI for the LS Mean	6.62, 11.72	9.39, 13.97
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.51 (1.727)
95% CI for the LS Mean		-0.92, 5.94
p-value		0.1493
Hedges' g (Zuranolone vs. Placebo)		0.289
95% CI for Hedges' g		-0.1059, 0.6848

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-age-itta.rtf **Run Date:** 24SEP2025

3.3.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 3		
n	20	26
LS Mean (SE)	2.97 (1.323)	3.20 (1.153)
95% CI for the LS Mean	0.29, 5.64	0.87, 5.53
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.24 (1.759)
95% CI for the LS Mean		-3.32, 3.79
p-value		0.8933
Hedges' g (Zuranolone vs. Placebo)		0.039
95% CI for Hedges' g		-0.5435, 0.6225
Day 8		
n	22	29
LS Mean (SE)	7.64 (1.389)	6.17 (1.204)
95% CI for the LS Mean	4.84, 10.43	3.74, 8.59
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.47 (1.844)
95% CI for the LS Mean		-5.18, 2.24
p-value		0.4296
Hedges' g (Zuranolone vs. Placebo)		-0.222
95% CI for Hedges' g		-0.7776, 0.3340

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	7.86 (1.706)	8.86 (1.480)
95% CI for the LS Mean	4.43, 11.29	5.88, 11.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.00 (2.264)
95% CI for the LS Mean		-3.56, 5.55
p-value		0.6619
Hedges' g (Zuranolone vs. Placebo)		0.123
95% CI for Hedges' g		-0.4355, 0.6823
Day 21		
n	22	28
LS Mean (SE)	9.45 (1.564)	7.98 (1.362)
95% CI for the LS Mean	6.31, 12.60	5.24, 10.71
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.48 (2.079)
95% CI for the LS Mean		-5.66, 2.70
p-value		0.4810
Hedges' g (Zuranolone vs. Placebo)		-0.199
95% CI for Hedges' g		-0.7589, 0.3606

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 45		
n	22	28
LS Mean (SE)	10.36 (1.856)	11.63 (1.626)
95% CI for the LS Mean	6.63, 14.10	8.36, 14.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.27 (2.473)
95% CI for the LS Mean		-3.71, 6.24
p-value		0.6110
Hedges' g (Zuranolone vs. Placebo)		0.144
95% CI for Hedges' g		-0.4155, 0.7027

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 3		
n	52	46
LS Mean (SE)	2.17 (0.758)	2.97 (0.806)
95% CI for the LS Mean	0.67, 3.67	1.37, 4.57
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.80 (1.108)
95% CI for the LS Mean		-1.40, 3.00
p-value		0.4699
Hedges' g (Zuranolone vs. Placebo)		0.146
95% CI for Hedges' g		-0.2515, 0.5430
Day 8		
n	52	46
LS Mean (SE)	5.09 (0.902)	5.45 (0.960)
95% CI for the LS Mean	3.30, 6.88	3.55, 7.36
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.36 (1.318)
95% CI for the LS Mean		-2.26, 2.98
p-value		0.7860
Hedges' g (Zuranolone vs. Placebo)		0.055
95% CI for Hedges' g		-0.3421, 0.4515

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	5.82 (1.063)	7.52 (1.128)
95% CI for the LS Mean	3.71, 7.94	5.28, 9.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.69 (1.551)
95% CI for the LS Mean		-1.39, 4.77
p-value		0.2783
Hedges' g (Zuranolone vs. Placebo)		0.220
95% CI for Hedges' g		-0.1798, 0.6197
Day 21		
n	51	46
LS Mean (SE)	6.80 (1.124)	8.52 (1.192)
95% CI for the LS Mean	4.57, 9.03	6.15, 10.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.71 (1.640)
95% CI for the LS Mean		-1.54, 4.97
p-value		0.2982
Hedges' g (Zuranolone vs. Placebo)		0.211
95% CI for Hedges' g		-0.1886, 0.6106

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 45		
n	47	45
LS Mean (SE)	8.95 (1.172)	11.94 (1.222)
95% CI for the LS Mean	6.62, 11.28	9.52, 14.37
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.00 (1.694)
95% CI for the LS Mean		-0.37, 6.36
p-value		0.0804
Hedges' g (Zuranolone vs. Placebo)		0.366
95% CI for Hedges' g		-0.0464, 0.7779

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

3.3.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 3		
n	31	29
LS Mean (SE)	2.41 (1.117)	1.86 (1.132)
95% CI for the LS Mean	0.17, 4.65	-0.41, 4.13
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.55 (1.592)
95% CI for the LS Mean		-3.74, 2.64
p-value		0.7326
Hedges' g (Zuranolone vs. Placebo)		-0.088
95% CI for Hedges' g		-0.5941, 0.4190
Day 8		
n	31	31
LS Mean (SE)	5.60 (1.195)	5.13 (1.197)
95% CI for the LS Mean	3.21, 7.99	2.73, 7.52
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.47 (1.694)
95% CI for the LS Mean		-3.86, 2.92
p-value		0.7811
Hedges' g (Zuranolone vs. Placebo)		-0.070
95% CI for Hedges' g		-0.5680, 0.4280

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	5.70 (1.324)	7.29 (1.326)
95% CI for the LS Mean	3.05, 8.35	4.63, 9.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.59 (1.876)
95% CI for the LS Mean		-2.17, 5.35
p-value		0.3999
Hedges' g (Zuranolone vs. Placebo)		0.213
95% CI for Hedges' g		-0.2865, 0.7120
Day 21		
n	31	30
LS Mean (SE)	6.92 (1.393)	7.63 (1.404)
95% CI for the LS Mean	4.13, 9.71	4.82, 10.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.70 (1.980)
95% CI for the LS Mean		-3.26, 4.67
p-value		0.7236
Hedges' g (Zuranolone vs. Placebo)		0.090
95% CI for Hedges' g		-0.4123, 0.5921

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 45		
n	30	30
LS Mean (SE)	9.03 (1.671)	11.06 (1.674)
95% CI for the LS Mean	5.69, 12.38	7.71, 14.41
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.03 (2.367)
95% CI for the LS Mean		-2.71, 6.76
p-value		0.3955
Hedges' g (Zuranolone vs. Placebo)		0.218
95% CI for Hedges' g		-0.2894, 0.7257

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 3		
n	39	42
LS Mean (SE)	2.22 (0.804)	4.00 (0.774)
95% CI for the LS Mean	0.62, 3.82	2.46, 5.54
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.78 (1.116)
95% CI for the LS Mean		-0.44, 4.01
p-value		0.1141
Hedges' g (Zuranolone vs. Placebo)		0.352
95% CI for Hedges' g		-0.0872, 0.7912
Day 8		
n	40	43
LS Mean (SE)	5.73 (1.054)	6.31 (1.010)
95% CI for the LS Mean	3.63, 7.83	4.30, 8.32
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.58 (1.460)
95% CI for the LS Mean		-2.33, 3.48
p-value		0.6930
Hedges' g (Zuranolone vs. Placebo)		0.086
95% CI for Hedges' g		-0.3445, 0.5170

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	6.83 (1.317)	8.79 (1.262)
95% CI for the LS Mean	4.21, 9.45	6.27, 11.30
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.96 (1.824)
95% CI for the LS Mean		-1.67, 5.59
p-value		0.2863
Hedges' g (Zuranolone vs. Placebo)		0.236
95% CI for Hedges' g		-0.2009, 0.6738
Day 21		
n	39	43
LS Mean (SE)	7.87 (1.302)	9.25 (1.243)
95% CI for the LS Mean	5.28, 10.46	6.77, 11.72
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.38 (1.800)
95% CI for the LS Mean		-2.21, 4.96
p-value		0.4473
Hedges' g (Zuranolone vs. Placebo)		0.167
95% CI for Hedges' g		-0.2668, 0.6015

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 45		
n	36	42
LS Mean (SE)	9.31 (1.312)	12.69 (1.239)
95% CI for the LS Mean	6.70, 11.92	10.23, 15.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.39 (1.804)
95% CI for the LS Mean		-0.21, 6.98
p-value		0.0644
Hedges' g (Zuranolone vs. Placebo)		0.422
95% CI for Hedges' g		-0.0279, 0.8722

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-race-itta.rtf **Run Date:** 24SEP2025

3.3.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 3		
n	13	14
LS Mean (SE)	3.10 (1.070)	2.19 (1.034)
95% CI for the LS Mean	0.89, 5.31	0.06, 4.32
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.91 (1.496)
95% CI for the LS Mean		-3.99, 2.17
p-value		0.5491
Hedges' g (Zuranolone vs. Placebo)		-0.227
95% CI for Hedges' g		-0.9842, 0.5304
Day 8		
n	13	16
LS Mean (SE)	6.94 (1.793)	6.61 (1.615)
95% CI for the LS Mean	3.26, 10.63	3.28, 9.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.34 (2.415)
95% CI for the LS Mean		-5.30, 4.63
p-value		0.8897
Hedges' g (Zuranolone vs. Placebo)		-0.051
95% CI for Hedges' g		-0.7828, 0.6811

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 2 of 6

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	6.10 (2.045)	9.12 (1.865)
95% CI for the LS Mean	1.89, 10.31	5.29, 12.95
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.02 (2.769)
95% CI for the LS Mean		-2.68, 8.72
p-value		0.2854
Hedges' g (Zuranolone vs. Placebo)		0.401
95% CI for Hedges' g		-0.3487, 1.1515
Day 21		
n	12	15
LS Mean (SE)	7.54 (1.681)	8.68 (1.516)
95% CI for the LS Mean	4.09, 11.00	5.57, 11.80
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.14 (2.267)
95% CI for the LS Mean		-3.52, 5.80
p-value		0.6192
Hedges' g (Zuranolone vs. Placebo)		0.189
95% CI for Hedges' g		-0.5719, 0.9497

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 45		
n	11	15
LS Mean (SE)	8.01 (1.947)	10.68 (1.726)
95% CI for the LS Mean	3.99, 12.02	7.11, 14.25
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.67 (2.604)
95% CI for the LS Mean		-2.70, 8.05
p-value		0.3148
Hedges' g (Zuranolone vs. Placebo)		0.395
95% CI for Hedges' g		-0.3907, 1.1800

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 3		
n	59	58
LS Mean (SE)	2.17 (0.748)	3.13 (0.756)
95% CI for the LS Mean	0.69, 3.65	1.63, 4.62
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.95 (1.064)
95% CI for the LS Mean		-1.15, 3.06
p-value		0.3717
Hedges' g (Zuranolone vs. Placebo)		0.165
95% CI for Hedges' g		-0.1983, 0.5278
Day 8		
n	61	59
LS Mean (SE)	5.54 (0.849)	5.59 (0.860)
95% CI for the LS Mean	3.86, 7.22	3.88, 7.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.04 (1.209)
95% CI for the LS Mean		-2.35, 2.44
p-value		0.9706
Hedges' g (Zuranolone vs. Placebo)		0.007
95% CI for Hedges' g		-0.3512, 0.3646

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	6.43 (1.018)	7.85 (1.028)
95% CI for the LS Mean	4.42, 8.45	5.81, 9.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.42 (1.447)
95% CI for the LS Mean		-1.45, 4.28
p-value		0.3295
Hedges' g (Zuranolone vs. Placebo)		0.178
95% CI for Hedges' g		-0.1817, 0.5384
Day 21		
n	61	59
LS Mean (SE)	7.53 (1.061)	8.32 (1.073)
95% CI for the LS Mean	5.42, 9.63	6.19, 10.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.79 (1.510)
95% CI for the LS Mean		-2.20, 3.78
p-value		0.6018
Hedges' g (Zuranolone vs. Placebo)		0.095
95% CI for Hedges' g		-0.2632, 0.4530

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 45		
n	58	58
LS Mean (SE)	9.59 (1.144)	12.20 (1.149)
95% CI for the LS Mean	7.32, 11.85	9.93, 14.48
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.62 (1.622)
95% CI for the LS Mean		-0.59, 5.83
p-value		0.1092
Hedges' g (Zuranolone vs. Placebo)		0.298
95% CI for Hedges' g		-0.0681, 0.6638

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

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3.3.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 3		
n	20	13
LS Mean (SE)	2.96 (1.242)	1.67 (1.541)
95% CI for the LS Mean	0.42, 5.50	-1.48, 4.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.28 (1.979)
95% CI for the LS Mean		-5.33, 2.76
p-value		0.5216
Hedges' g (Zuranolone vs. Placebo)		-0.225
95% CI for Hedges' g		-0.9258, 0.4749
Day 8		
n	20	13
LS Mean (SE)	6.16 (1.573)	3.83 (1.952)
95% CI for the LS Mean	2.94, 9.37	-0.16, 7.81
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.33 (2.507)
95% CI for the LS Mean		-7.45, 2.79
p-value		0.3600
Hedges' g (Zuranolone vs. Placebo)		-0.323
95% CI for Hedges' g		-1.0257, 0.3795

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	6.16 (1.864)	7.13 (2.312)
95% CI for the LS Mean	2.35, 9.96	2.41, 11.86
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.98 (2.969)
95% CI for the LS Mean		-5.09, 7.04
p-value		0.7442
Hedges' g (Zuranolone vs. Placebo)		0.114
95% CI for Hedges' g		-0.5843, 0.8133
Day 21		
n	19	12
LS Mean (SE)	6.72 (1.900)	9.26 (2.372)
95% CI for the LS Mean	2.84, 10.60	4.42, 14.10
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.54 (3.039)
95% CI for the LS Mean		-3.66, 8.75
p-value		0.4097
Hedges' g (Zuranolone vs. Placebo)		0.300
95% CI for Hedges' g		-0.4263, 1.0268

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 45		
n	18	12
LS Mean (SE)	7.84 (2.145)	13.20 (2.636)
95% CI for the LS Mean	3.44, 12.23	7.81, 18.60
Difference (Zuranolone - Placebo)		
LS Mean (SE)		5.37 (3.398)
95% CI for the LS Mean		-1.59, 12.33
p-value		0.1252
Hedges' g (Zuranolone vs. Placebo)		0.573
95% CI for Hedges' g		-0.1717, 1.3177

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 3		
n	19	20
LS Mean (SE)	1.69 (1.324)	5.46 (1.298)
95% CI for the LS Mean	-1.00, 4.37	2.83, 8.10
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.78 (1.859)
95% CI for the LS Mean		0.01, 7.55
p-value		0.0496
Hedges' g (Zuranolone vs. Placebo)		0.638
95% CI for Hedges' g		-0.0060, 1.2813
Day 8		
n	20	20
LS Mean (SE)	4.51 (1.506)	7.99 (1.487)
95% CI for the LS Mean	1.45, 7.56	4.97, 11.00
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.48 (2.120)
95% CI for the LS Mean		-0.82, 7.77
p-value		0.1096
Hedges' g (Zuranolone vs. Placebo)		0.508
95% CI for Hedges' g		-0.1215, 1.1380

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NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	4.96 (1.914)	9.59 (1.879)
95% CI for the LS Mean	1.08, 8.84	5.78, 13.40
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.63 (2.685)
95% CI for the LS Mean		-0.81, 10.07
p-value		0.0928
Hedges' g (Zuranolone vs. Placebo)		0.535
95% CI for Hedges' g		-0.0959, 1.1657
Day 21		
n	20	21
LS Mean (SE)	7.86 (2.074)	11.24 (2.022)
95% CI for the LS Mean	3.66, 12.06	7.14, 15.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.38 (2.898)
95% CI for the LS Mean		-2.49, 9.25
p-value		0.2513
Hedges' g (Zuranolone vs. Placebo)		0.357
95% CI for Hedges' g		-0.2602, 0.9743

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 45		
n	20	20
LS Mean (SE)	9.66 (2.031)	13.48 (1.996)
95% CI for the LS Mean	5.53, 13.78	9.43, 17.53
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.82 (2.850)
95% CI for the LS Mean		-1.96, 9.60
p-value		0.1886
Hedges' g (Zuranolone vs. Placebo)		0.416
95% CI for Hedges' g		-0.2109, 1.0420

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NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 3		
n	33	39
LS Mean (SE)	2.37 (0.868)	2.29 (0.794)
95% CI for the LS Mean	0.63, 4.10	0.71, 3.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.07 (1.177)
95% CI for the LS Mean		-2.43, 2.28
p-value		0.9495
Hedges' g (Zuranolone vs. Placebo)		-0.015
95% CI for Hedges' g		-0.4785, 0.4487
Day 8		
n	34	42
LS Mean (SE)	6.30 (1.080)	5.36 (0.972)
95% CI for the LS Mean	4.15, 8.45	3.43, 7.30
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.94 (1.453)
95% CI for the LS Mean		-3.84, 1.96
p-value		0.5204
Hedges' g (Zuranolone vs. Placebo)		-0.148
95% CI for Hedges' g		-0.6003, 0.3053

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	7.30 (1.200)	7.66 (1.082)
95% CI for the LS Mean	4.91, 9.69	5.50, 9.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.36 (1.616)
95% CI for the LS Mean		-2.86, 3.58
p-value		0.8259
Hedges' g (Zuranolone vs. Placebo)		0.051
95% CI for Hedges' g		-0.4074, 0.5095
Day 21		
n	34	41
LS Mean (SE)	7.77 (1.149)	6.77 (1.041)
95% CI for the LS Mean	5.48, 10.06	4.70, 8.85
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.00 (1.551)
95% CI for the LS Mean		-4.09, 2.09
p-value		0.5222
Hedges' g (Zuranolone vs. Placebo)		-0.148
95% CI for Hedges' g		-0.6029, 0.3076

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 45		
n	31	41
LS Mean (SE)	9.91 (1.409)	10.71 (1.247)
95% CI for the LS Mean	7.10, 12.71	8.22, 13.19
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.80 (1.882)
95% CI for the LS Mean		-2.95, 4.55
p-value		0.6717
Hedges' g (Zuranolone vs. Placebo)		0.100
95% CI for Hedges' g		-0.3666, 0.5670

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

3.3.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 3		
n	31	32
LS Mean (SE)	2.67 (1.001)	2.88 (0.985)
95% CI for the LS Mean	0.66, 4.67	0.91, 4.85
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.21 (1.409)
95% CI for the LS Mean		-2.61, 3.04
p-value		0.8796
Hedges' g (Zuranolone vs. Placebo)		0.038
95% CI for Hedges' g		-0.4561, 0.5319
Day 8		
n	31	32
LS Mean (SE)	4.89 (1.136)	5.19 (1.117)
95% CI for the LS Mean	2.62, 7.16	2.96, 7.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.30 (1.597)
95% CI for the LS Mean		-2.89, 3.50
p-value		0.8511
Hedges' g (Zuranolone vs. Placebo)		0.047
95% CI for Hedges' g		-0.4471, 0.5409

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	4.96 (1.409)	7.32 (1.386)
95% CI for the LS Mean	2.14, 7.78	4.54, 10.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.36 (1.980)
95% CI for the LS Mean		-1.60, 6.32
p-value		0.2377
Hedges' g (Zuranolone vs. Placebo)		0.297
95% CI for Hedges' g		-0.1997, 0.7936
Day 21		
n	30	31
LS Mean (SE)	7.54 (1.531)	8.29 (1.506)
95% CI for the LS Mean	4.48, 10.60	5.27, 11.30
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.75 (2.150)
95% CI for the LS Mean		-3.55, 5.05
p-value		0.7288
Hedges' g (Zuranolone vs. Placebo)		0.088
95% CI for Hedges' g		-0.4142, 0.5903

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 45		
n	29	30
LS Mean (SE)	9.31 (1.511)	11.20 (1.486)
95% CI for the LS Mean	6.28, 12.33	8.23, 14.18
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.89 (2.122)
95% CI for the LS Mean		-2.36, 6.14
p-value		0.3761
Hedges' g (Zuranolone vs. Placebo)		0.229
95% CI for Hedges' g		-0.2829, 0.7413

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.
Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 3		
n	41	40
LS Mean (SE)	2.08 (0.874)	3.23 (0.879)
95% CI for the LS Mean	0.34, 3.82	1.48, 4.98
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.15 (1.243)
95% CI for the LS Mean		-1.33, 3.63
p-value		0.3578
Hedges' g (Zuranolone vs. Placebo)		0.204
95% CI for Hedges' g		-0.2331, 0.6403
Day 8		
n	43	43
LS Mean (SE)	6.44 (1.031)	6.23 (1.026)
95% CI for the LS Mean	4.39, 8.49	4.19, 8.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.21 (1.460)
95% CI for the LS Mean		-3.12, 2.69
p-value		0.8849
Hedges' g (Zuranolone vs. Placebo)		-0.031
95% CI for Hedges' g		-0.4538, 0.3917

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	7.40 (1.167)	8.68 (1.161)
95% CI for the LS Mean	5.08, 9.73	6.37, 10.99
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.27 (1.651)
95% CI for the LS Mean		-2.01, 4.56
p-value		0.4424
Hedges' g (Zuranolone vs. Placebo)		0.167
95% CI for Hedges' g		-0.2616, 0.5953
Day 21		
n	43	43
LS Mean (SE)	7.53 (1.147)	8.48 (1.142)
95% CI for the LS Mean	5.25, 9.81	6.21, 10.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.95 (1.623)
95% CI for the LS Mean		-2.28, 4.17
p-value		0.5614
Hedges' g (Zuranolone vs. Placebo)		0.125
95% CI for Hedges' g		-0.2985, 0.5477

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 45		
n	40	43
LS Mean (SE)	9.36 (1.342)	12.44 (1.317)
95% CI for the LS Mean	6.69, 12.03	9.82, 15.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.08 (1.884)
95% CI for the LS Mean		-0.67, 6.83
p-value		0.1062
Hedges' g (Zuranolone vs. Placebo)		0.356
95% CI for Hedges' g		-0.0783, 0.7895

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-onset-itta.rtf **Run Date:** 24SEP2025

3.3.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 3		
n	10	10
LS Mean (SE)	3.04 (1.214)	5.10 (1.218)
95% CI for the LS Mean	0.47, 5.60	2.53, 7.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.06 (1.775)
95% CI for the LS Mean		-1.68, 5.80
p-value		0.2616
Hedges' g (Zuranolone vs. Placebo)		0.497
95% CI for Hedges' g		-0.3930, 1.3869
Day 8		
n	10	10
LS Mean (SE)	7.24 (2.014)	5.00 (2.016)
95% CI for the LS Mean	2.95, 11.52	0.71, 9.28
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.24 (2.883)
95% CI for the LS Mean		-8.36, 3.88
p-value		0.4484
Hedges' g (Zuranolone vs. Placebo)		-0.333
95% CI for Hedges' g		-1.2155, 0.5496

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	6.64 (2.249)	7.60 (2.251)
95% CI for the LS Mean	1.88, 11.39	2.84, 12.35
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.96 (3.212)
95% CI for the LS Mean		-5.82, 7.73
p-value		0.7689
Hedges' g (Zuranolone vs. Placebo)		0.128
95% CI for Hedges' g		-0.7495, 1.0053
Day 21		
n	10	10
LS Mean (SE)	6.64 (2.159)	7.70 (2.161)
95% CI for the LS Mean	2.08, 11.20	3.13, 12.26
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.06 (3.086)
95% CI for the LS Mean		-5.45, 7.57
p-value		0.7356
Hedges' g (Zuranolone vs. Placebo)		0.147
95% CI for Hedges' g		-0.7307, 1.0247

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 45		
n	9	10
LS Mean (SE)	10.57 (1.697)	9.20 (1.647)
95% CI for the LS Mean	7.00, 14.15	5.71, 12.68
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.38 (2.414)
95% CI for the LS Mean		-6.46, 3.71
p-value		0.5757
Hedges' g (Zuranolone vs. Placebo)		-0.250
95% CI for Hedges' g		-1.1545, 0.6537

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 3		
n	62	62
LS Mean (SE)	2.10 (0.725)	2.90 (0.721)
95% CI for the LS Mean	0.66, 3.53	1.48, 4.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.81 (1.023)
95% CI for the LS Mean		-1.22, 2.83
p-value		0.4312
Hedges' g (Zuranolone vs. Placebo)		0.141
95% CI for Hedges' g		-0.2115, 0.4934
Day 8		
n	64	65
LS Mean (SE)	5.44 (0.833)	6.05 (0.824)
95% CI for the LS Mean	3.79, 7.09	4.42, 7.68
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.61 (1.172)
95% CI for the LS Mean		-1.71, 2.93
p-value		0.6048
Hedges' g (Zuranolone vs. Placebo)		0.091
95% CI for Hedges' g		-0.2545, 0.4361

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	6.21 (0.996)	8.31 (0.984)
95% CI for the LS Mean	4.24, 8.18	6.36, 10.26
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.10 (1.401)
95% CI for the LS Mean		-0.67, 4.87
p-value		0.1363
Hedges' g (Zuranolone vs. Placebo)		0.264
95% CI for Hedges' g		-0.0849, 0.6138
Day 21		
n	63	64
LS Mean (SE)	7.54 (1.017)	8.65 (1.005)
95% CI for the LS Mean	5.53, 9.56	6.66, 10.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.10 (1.430)
95% CI for the LS Mean		-1.73, 3.93
p-value		0.4420
Hedges' g (Zuranolone vs. Placebo)		0.136
95% CI for Hedges' g		-0.2122, 0.4843

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 45		
n	60	63
LS Mean (SE)	8.90 (1.118)	12.43 (1.098)
95% CI for the LS Mean	6.69, 11.12	10.25, 14.60
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.53 (1.567)
95% CI for the LS Mean		0.42, 6.63
p-value		0.0263
Hedges' g (Zuranolone vs. Placebo)		0.403
95% CI for Hedges' g		0.0462, 0.7604

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/t-bimf-need-mmrm-201-by.sas:t-bimf-need-mmrm-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

3.3.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 3		
n	58	62
LS Mean (SE)	2.73 (0.729)	2.93 (0.699)
95% CI for the LS Mean	1.29, 4.17	1.54, 4.31
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.20 (1.011)
95% CI for the LS Mean		-1.80, 2.20
p-value		0.8437
Hedges' g (Zuranolone vs. Placebo)		0.036
95% CI for Hedges' g		-0.3222, 0.3939
Day 8		
n	59	65
LS Mean (SE)	6.29 (0.854)	5.45 (0.810)
95% CI for the LS Mean	4.59, 7.98	3.85, 7.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.83 (1.178)
95% CI for the LS Mean		-3.16, 1.50
p-value		0.4820
Hedges' g (Zuranolone vs. Placebo)		-0.126
95% CI for Hedges' g		-0.4788, 0.2268

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 6

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	7.10 (1.038)	8.11 (0.986)
95% CI for the LS Mean	5.04, 9.15	6.16, 10.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.01 (1.433)
95% CI for the LS Mean		-1.83, 3.85
p-value		0.4823
Hedges' g (Zuranolone vs. Placebo)		0.126
95% CI for Hedges' g		-0.2277, 0.4805
Day 21		
n	58	65
LS Mean (SE)	7.95 (1.038)	8.07 (0.983)
95% CI for the LS Mean	5.90, 10.01	6.13, 10.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.12 (1.430)
95% CI for the LS Mean		-2.71, 2.95
p-value		0.9320
Hedges' g (Zuranolone vs. Placebo)		0.015
95% CI for Hedges' g		-0.3387, 0.3694

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by History of PPD: 217-PPD-201B - ITT population

Page: 3 of 6

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 45		
n	55	64
LS Mean (SE)	9.78 (1.141)	12.02 (1.069)
95% CI for the LS Mean	7.52, 12.04	9.90, 14.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.24 (1.564)
95% CI for the LS Mean		-0.86, 5.34
p-value		0.1545
Hedges' g (Zuranolone vs. Placebo)		0.262
95% CI for Hedges' g		-0.1001, 0.6237

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 3		
n	14	10
LS Mean (SE)	0.83 (1.474)	4.13 (1.761)
95% CI for the LS Mean	-2.24, 3.89	0.46, 7.80
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.30 (2.390)
95% CI for the LS Mean		-1.67, 8.28
p-value		0.1814
Hedges' g (Zuranolone vs. Placebo)		0.553
95% CI for Hedges' g		-0.2737, 1.3791
Day 8		
n	15	10
LS Mean (SE)	3.88 (1.629)	7.93 (2.002)
95% CI for the LS Mean	0.50, 7.25	3.79, 12.07
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.06 (2.663)
95% CI for the LS Mean		-1.45, 9.56
p-value		0.1412
Hedges' g (Zuranolone vs. Placebo)		0.601
95% CI for Hedges' g		-0.2161, 1.4185

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by History of PPD: 217-PPD-201B - ITT population

Page: 5 of 6

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	3.56 (1.706)	8.03 (2.073)
95% CI for the LS Mean	0.03, 7.10	3.73, 12.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.47 (2.764)
95% CI for the LS Mean		-1.26, 10.19
p-value		0.1199
Hedges' g (Zuranolone vs. Placebo)		0.646
95% CI for Hedges' g		-0.1856, 1.4781
Day 21		
n	15	9
LS Mean (SE)	5.88 (1.875)	10.72 (2.394)
95% CI for the LS Mean	1.99, 9.76	5.78, 15.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		4.85 (3.119)
95% CI for the LS Mean		-1.58, 11.28
p-value		0.1330
Hedges' g (Zuranolone vs. Placebo)		0.633
95% CI for Hedges' g		-0.2130, 1.4781

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

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Model-based Results on Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by History of PPD: 217-PPD-201B - ITT population

Page: 6 of 6

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 45		
n	14	9
LS Mean (SE)	7.66 (2.057)	10.95 (2.598)
95% CI for the LS Mean	3.39, 11.92	5.59, 16.32
Difference (Zuranolone - Placebo)		
LS Mean (SE)		3.30 (3.386)
95% CI for the LS Mean		-3.69, 10.29
p-value		0.3396
Hedges' g (Zuranolone vs. Placebo)		0.401
95% CI for Hedges' g		-0.4442, 1.2466

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

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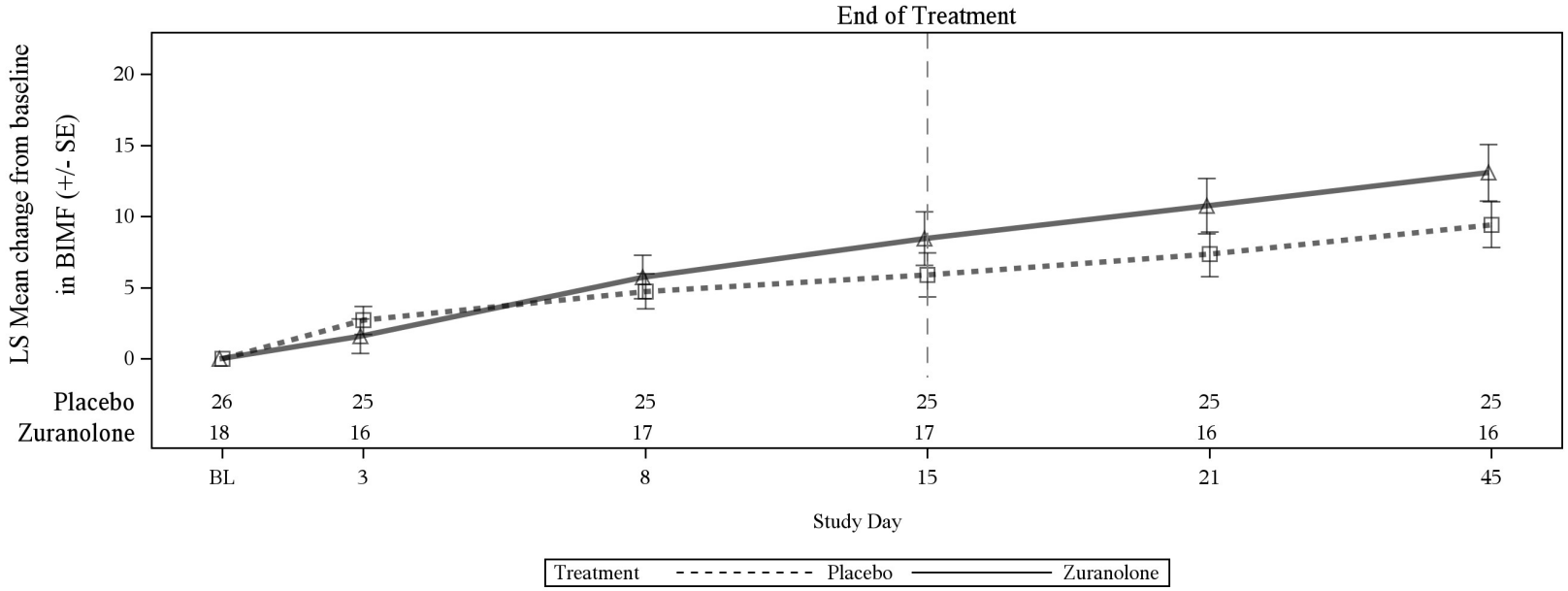
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3.3.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

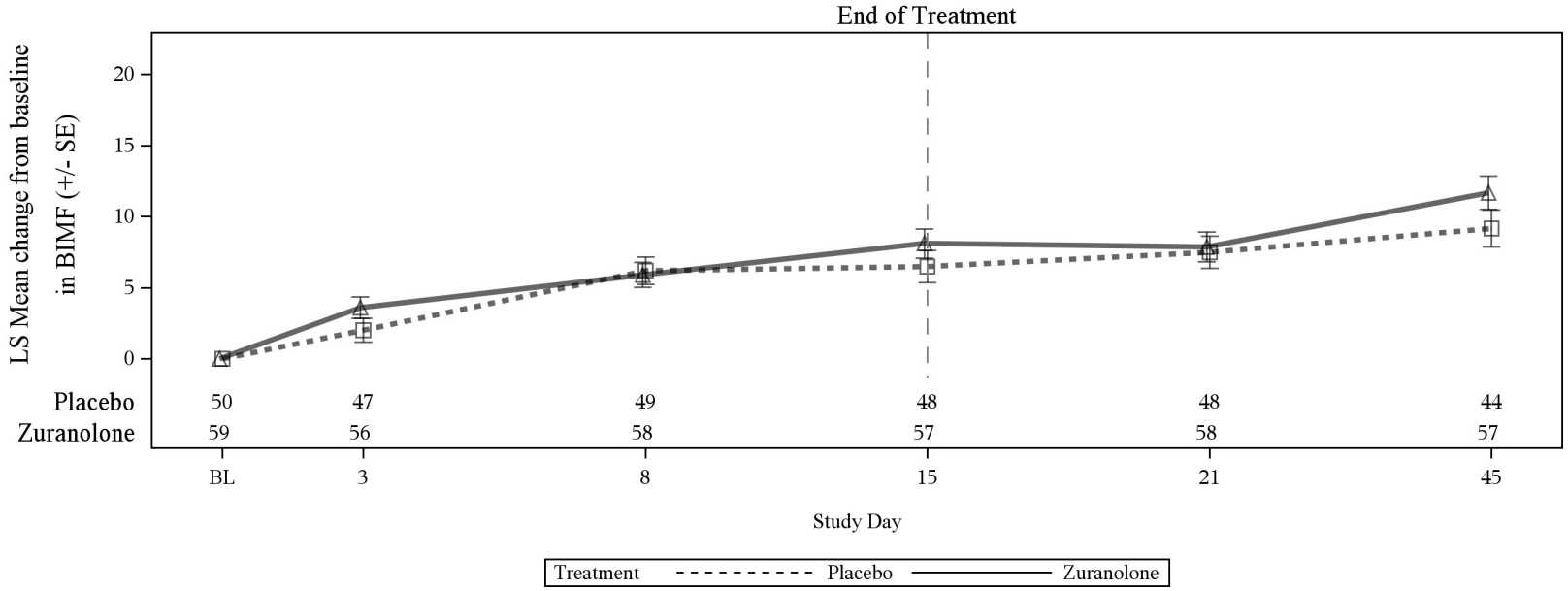
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

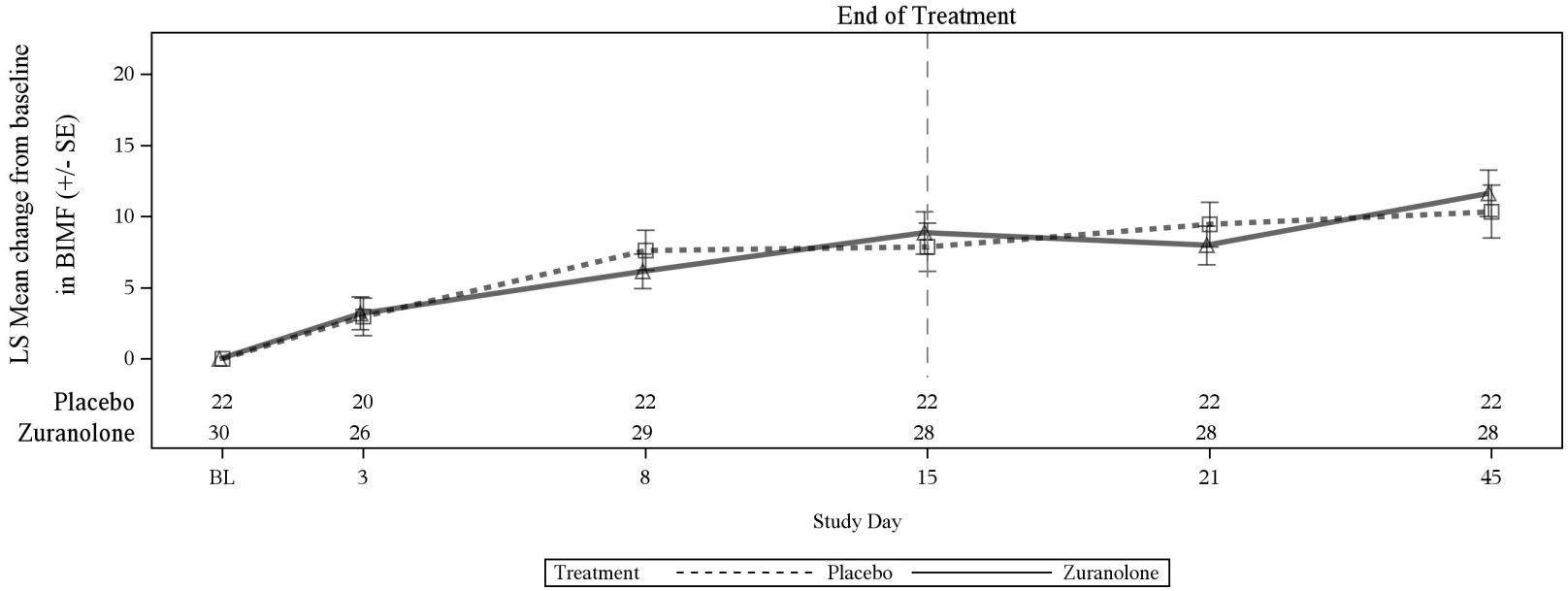
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

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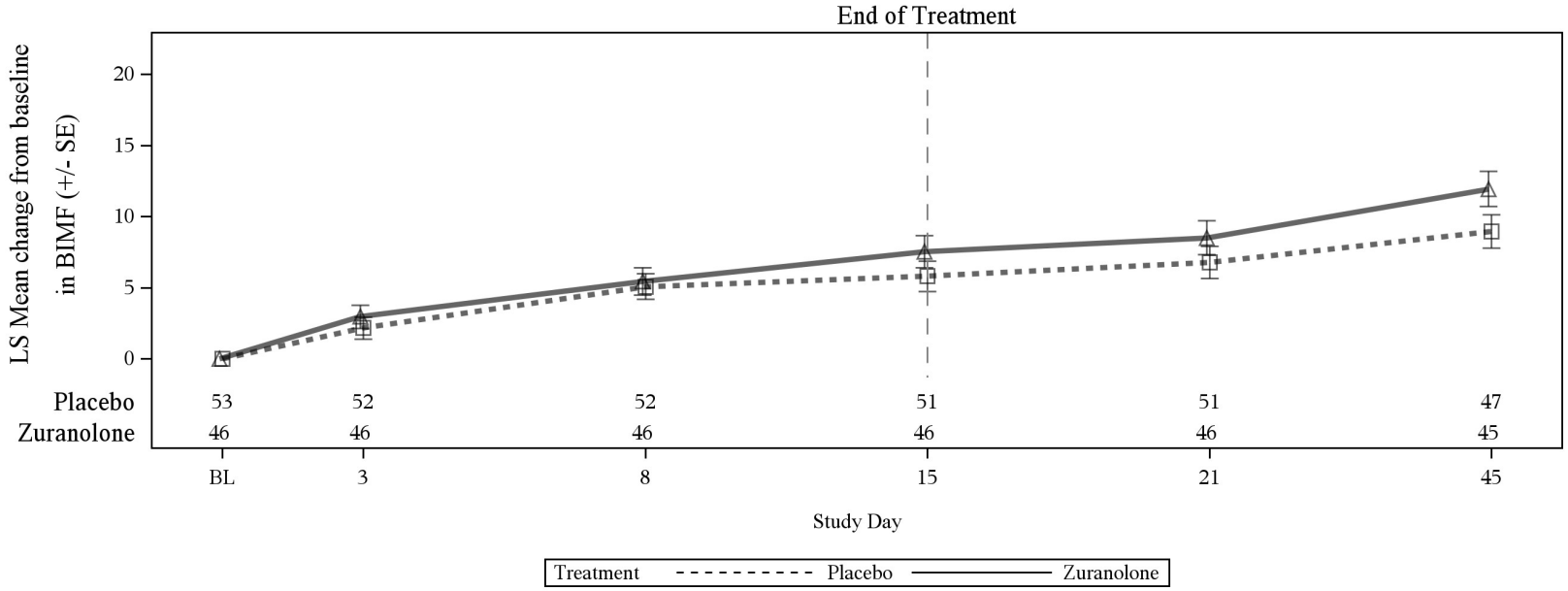
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

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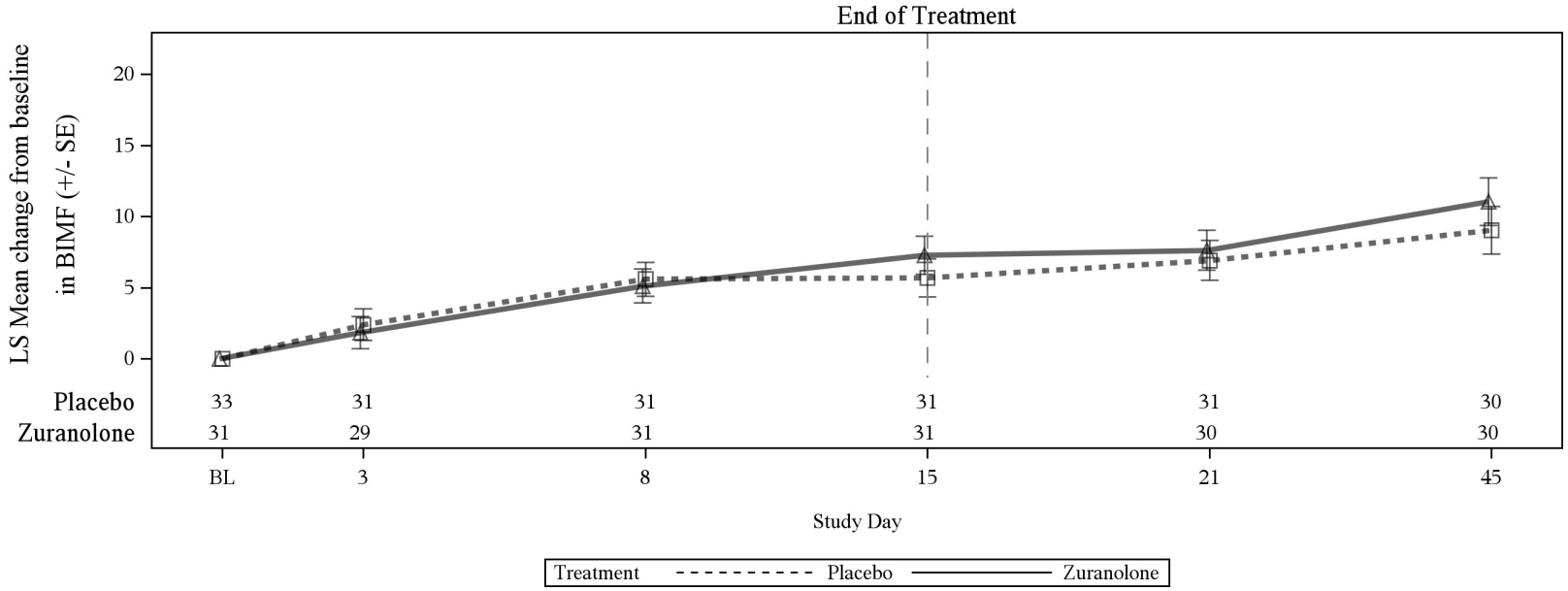
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

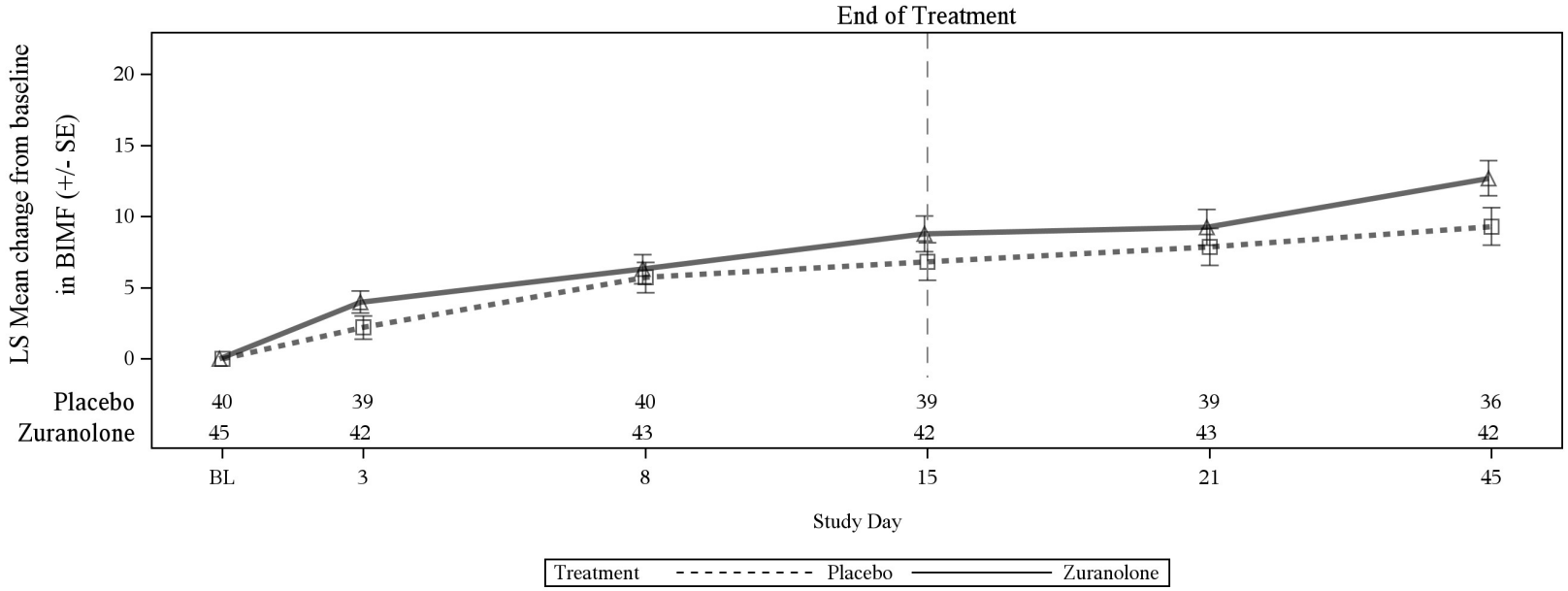
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

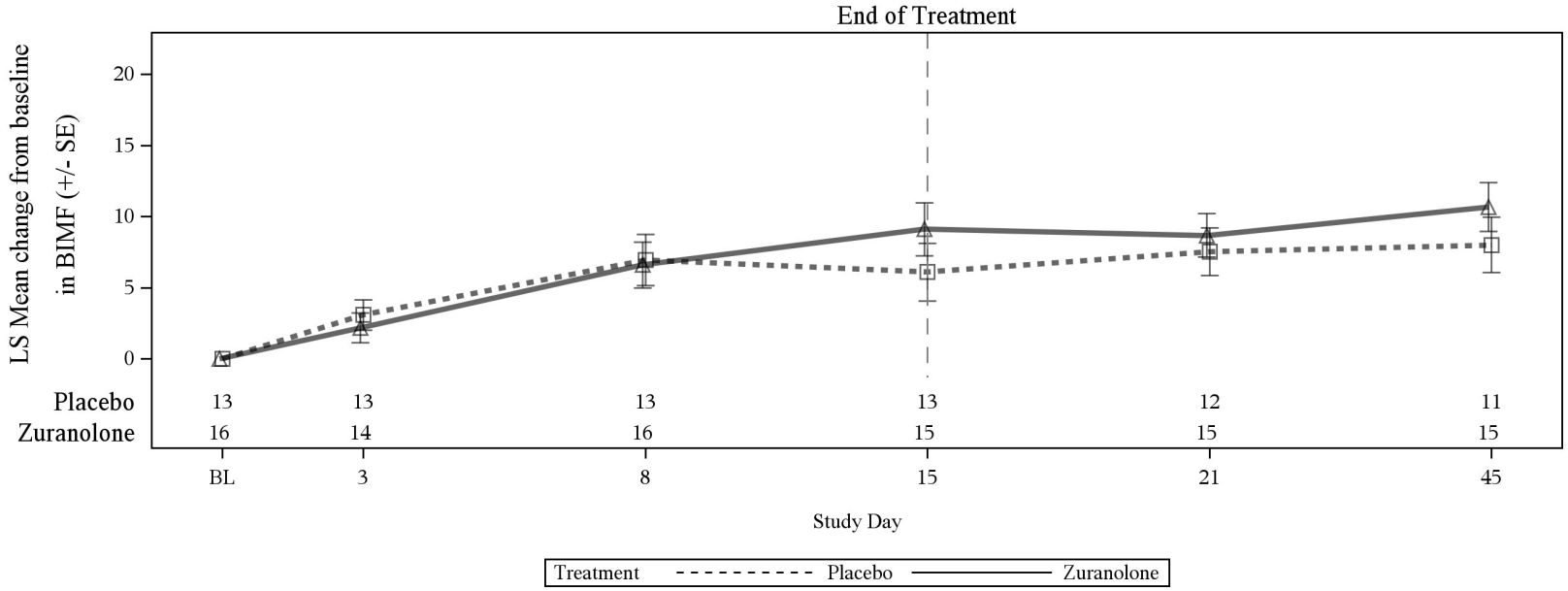
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

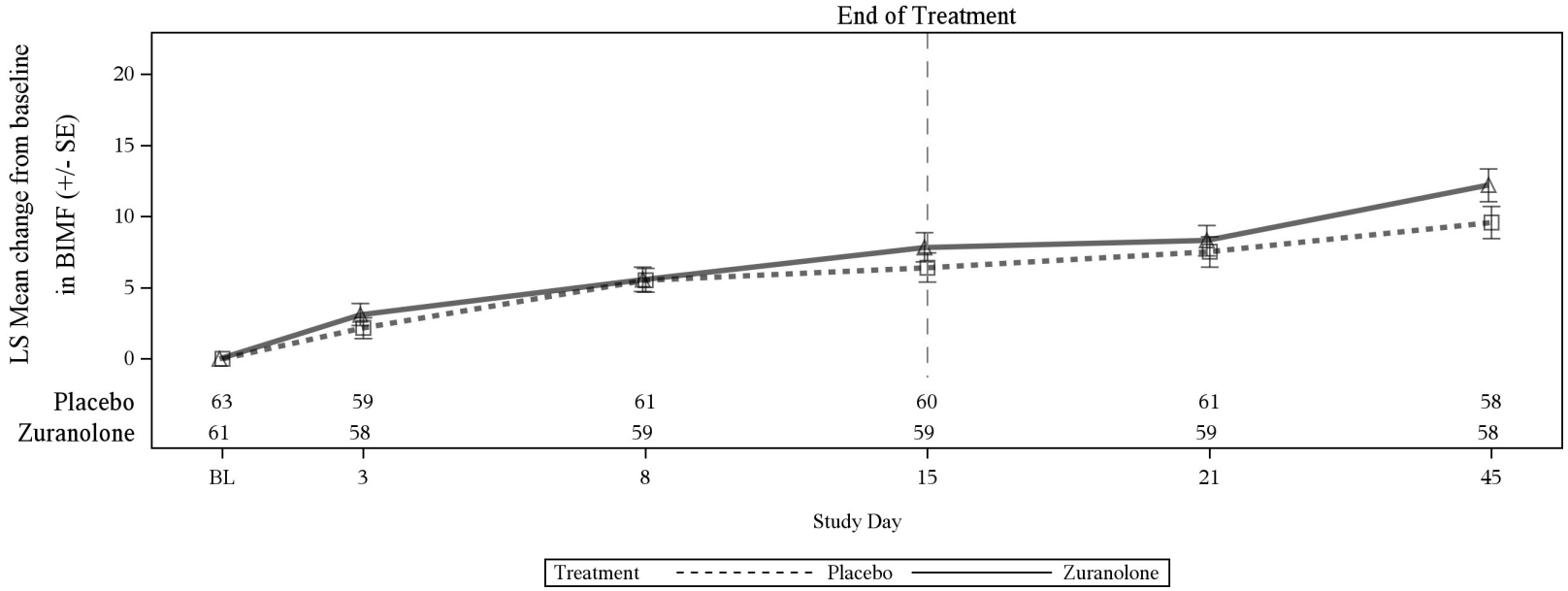
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

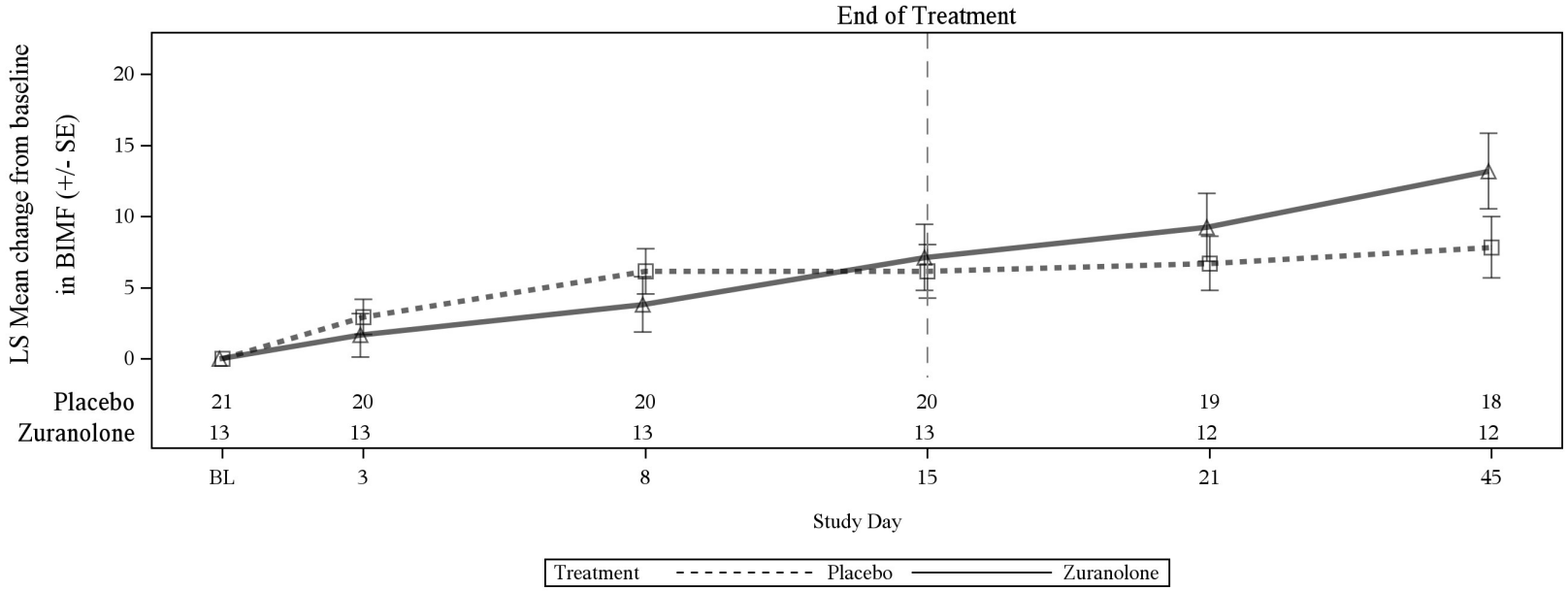
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

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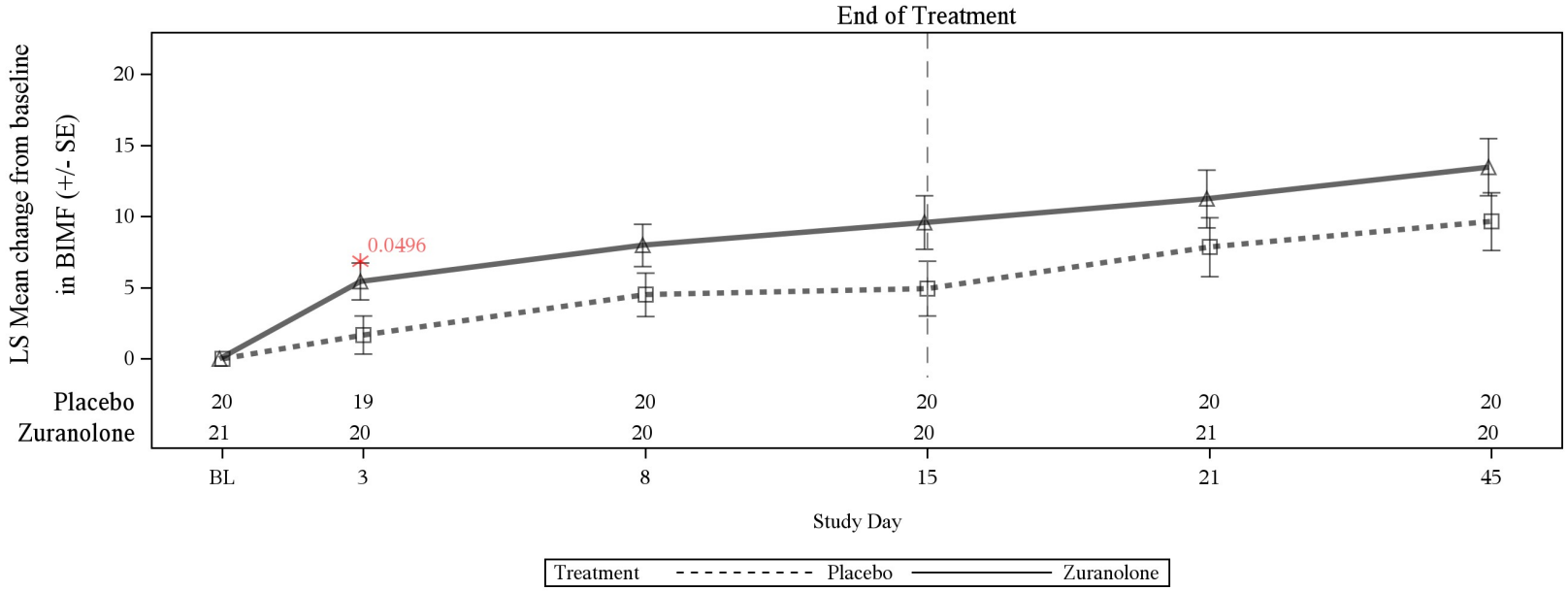
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Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

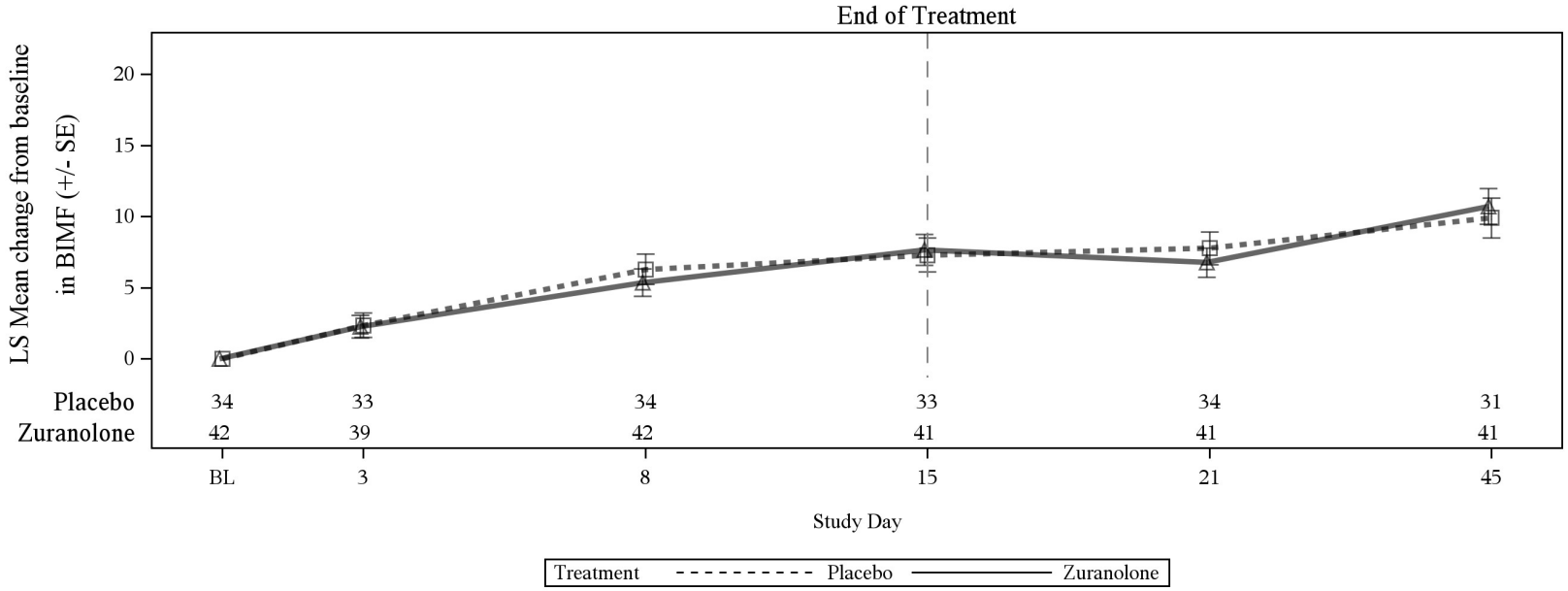
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-need-mmrm-201-by.sas:f-bimf-need-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

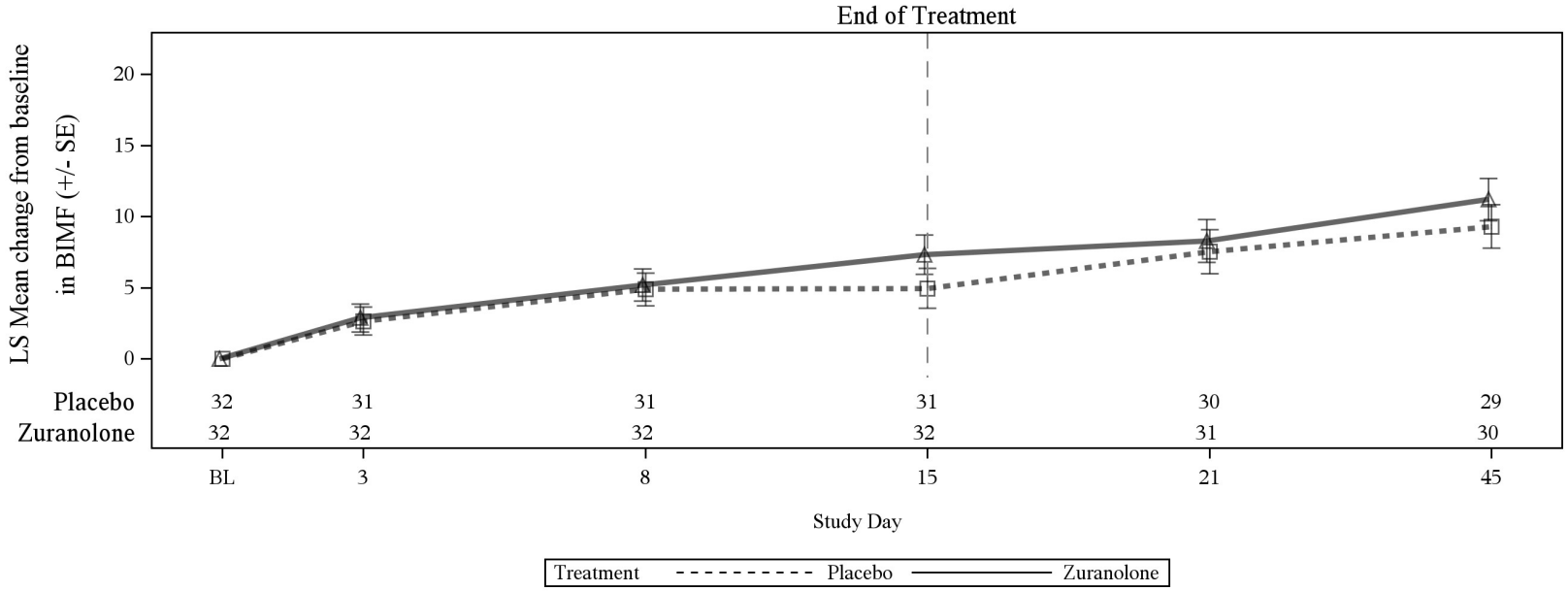
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-need-mmrm-201-by.sas:f-bimf-need-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

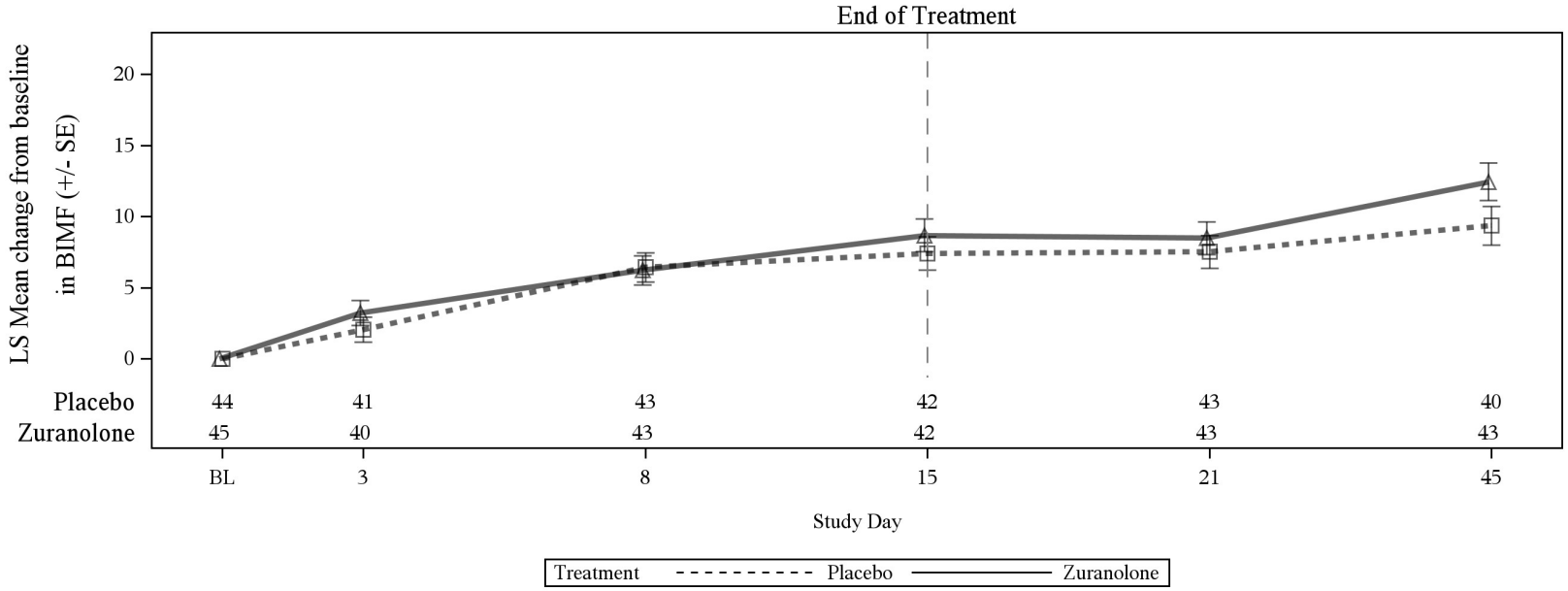
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-need-mmrm-201-by.sas:f-bimf-need-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

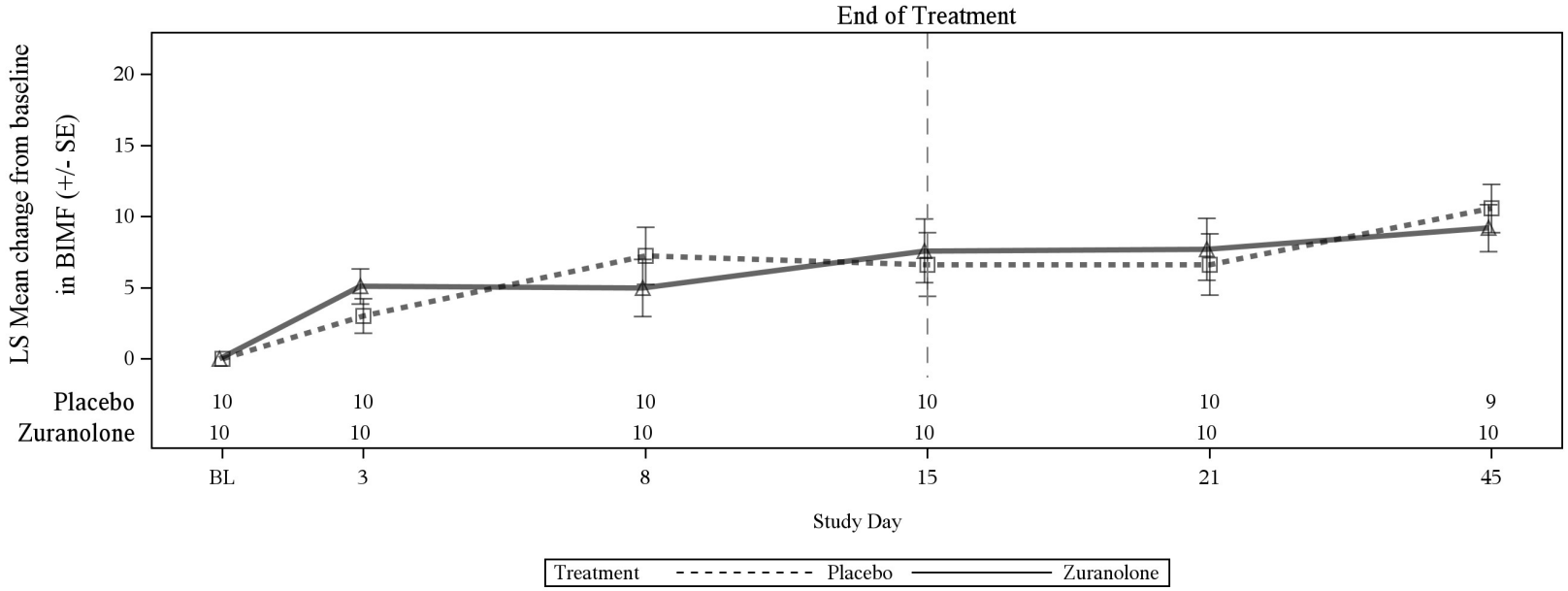
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-need-mmrm-201-by.sas:f-bimf-need-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

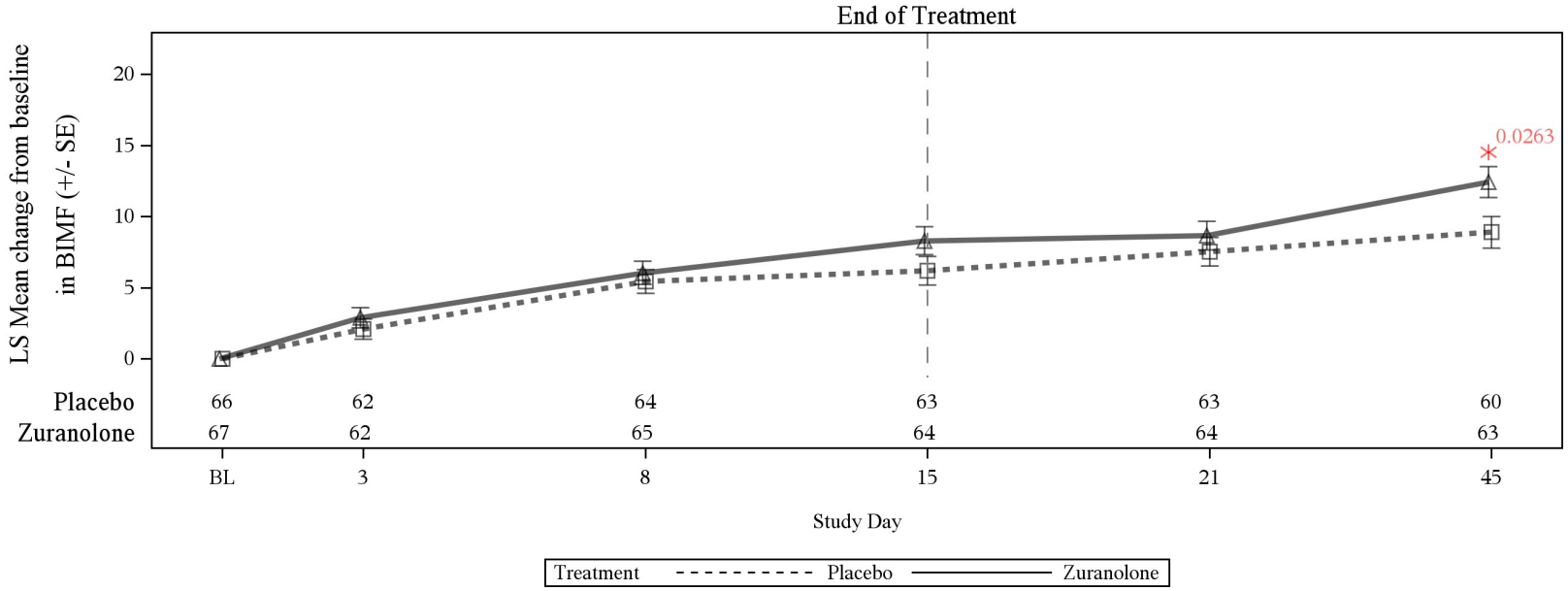
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-need-mmrm-201-by.sas:f-bimf-need-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

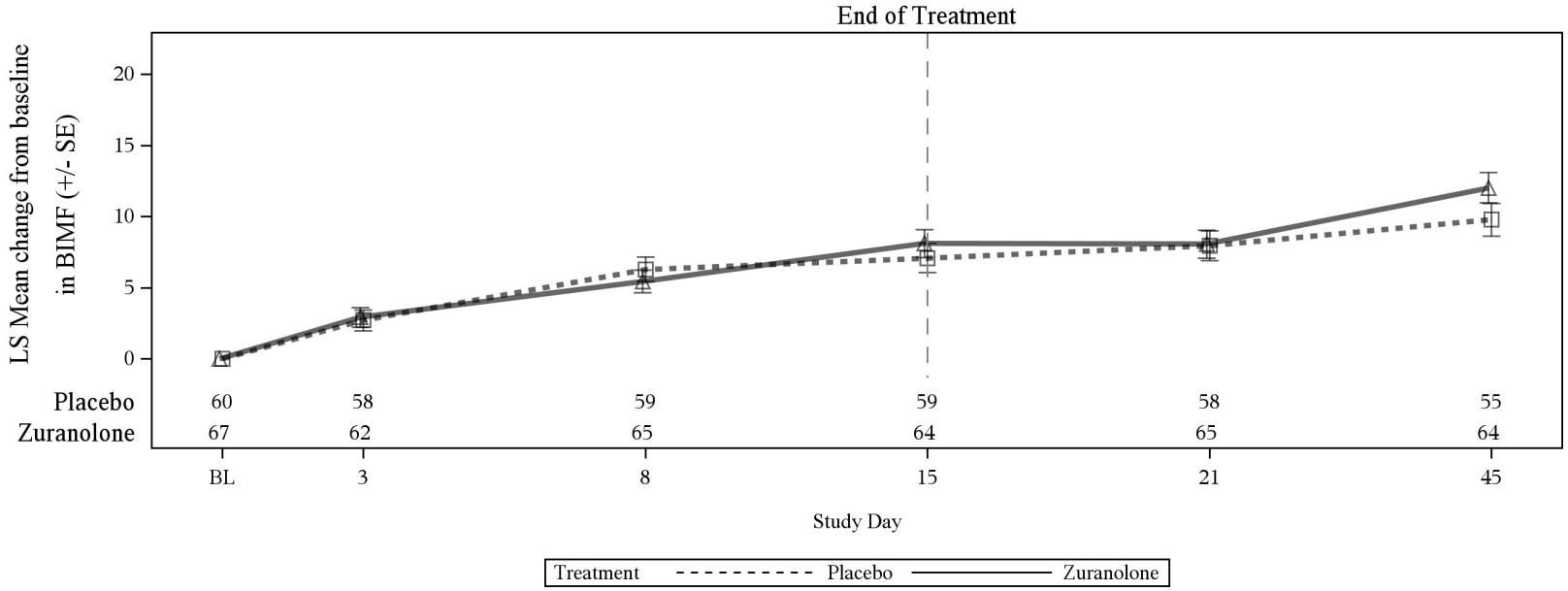
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-need-mmrm-201-by.sas:f-bimf-need-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

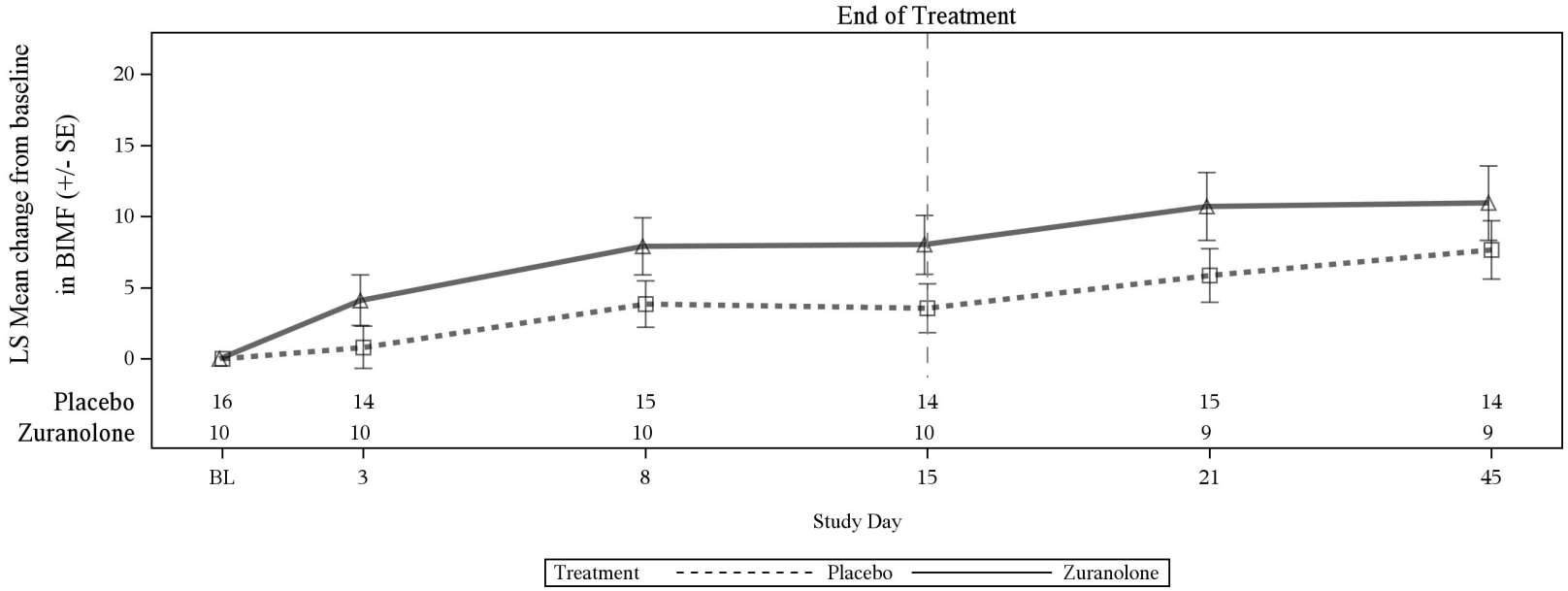
NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-need-mmrm-201-by.sas:f-bimf-need-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Score by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The BIMF total score was calculated as the sum of the 20 individual item scores (where questions 16 and 18 were reverse-scored), with a range from 0 to 120. The Mom's Competency subscale score was calculated as the sum of items 1, 3, 4, 5, 10, 12, 14, 15, 17, 19, and 20; the Mom's Needs subscale score was calculated as the sum of items 2, 6, 7, 8, 9, 11, and 13. A positive change indicates improvement.

Source: biib125/v_a/germany_amnog/f-bimf-need-mmrm-201-by.sas:f-bimf-need-mmrm-201-by-itta.rtf **Run Date:** 24SEP2025

3.3.2 Ansprechen

3.3.2.1 Responder-Analysen

3.3.2.1 .1 ITT-Population

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with a response, n (%) [2]	12 (16.0)	17 (22.4)
Number of subjects with missing evaluation, n (%)	3 (4.0)	4 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.372
95% CI for the RR		(0.706, 2.665)
p-value for RR		0.3505
OR - Odds Ratio (Zuranolone vs. Placebo)		1.409
95% CI for the OR		(0.625, 3.176)
p-value for OR		0.4080
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.
[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-ovr.sas:t-bimf-need-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 2 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with a response, n (%) [2]	33 (44.0)	31 (40.8)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.948
95% CI for the RR		(0.665, 1.352)
p-value for RR		0.7692
OR - Odds Ratio (Zuranolone vs. Placebo)		0.836
95% CI for the OR		(0.442, 1.583)
p-value for OR		0.5831
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-ovr.sas:t-bimf-need-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 3 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with a response, n (%) [2]	33 (44.0)	35 (46.1)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.054
95% CI for the RR		(0.747, 1.487)
p-value for RR		0.7654
OR - Odds Ratio (Zuranolone vs. Placebo)		1.050
95% CI for the OR		(0.539, 2.047)
p-value for OR		0.8850
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-ovr.sas:t-bimf-need-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with a response, n (%) [2]	40 (53.3)	32 (42.1)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.801
95% CI for the RR		(0.580, 1.107)
p-value for RR		0.1788
OR - Odds Ratio (Zuranolone vs. Placebo)		0.603
95% CI for the OR		(0.315, 1.153)
p-value for OR		0.1259
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-ovr.sas:t-bimf-need-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 5 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	41 (54.7)	50 (65.8)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.165
95% CI for the RR		(0.905, 1.501)
p-value for RR		0.2364
OR - Odds Ratio (Zuranolone vs. Placebo)		1.604
95% CI for the OR		(0.805, 3.194)
p-value for OR		0.1792
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-ovr.sas:t-bimf-need-resp15-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.3.2.1 .2 Subgruppen

3.3.2.1 .2 .1 Interaktionstest

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	33 (44.0)	35 (46.1)	
Number of subjects with response at Day 45, n (%)	41 (54.7)	50 (65.8)	
Age Group (years)			0.4535
Day 15			
18 - 24, n / N (%)	10/25 (40.0)	8/17 (47.1)	
25 - 45, n / N (%)	23/50 (46.0)	27/59 (45.8)	
Day 45			
18 - 24, n / N (%)	15/25 (60.0)	10/17 (58.8)	
25 - 45, n / N (%)	26/50 (52.0)	40/59 (67.8)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-int.sas:t-bimf-need-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.2066
Day 15			
<28, n / N (%)	12/22 (54.5)	14/30 (46.7)	
>=28, n / N (%)	21/53 (39.6)	21/46 (45.7)	
Day 45			
<28, n / N (%)	13/22 (59.1)	17/30 (56.7)	
>=28, n / N (%)	28/53 (52.8)	33/46 (71.7)	
Race Group (Black or African American, White)			0.2544
Day 15			
Black or African American, n / N (%)	13/32 (40.6)	13/31 (41.9)	
White, n / N (%)	18/40 (45.0)	22/44 (50.0)	
Day 45			
Black or African American, n / N (%)	18/32 (56.3)	18/31 (58.1)	
White, n / N (%)	20/40 (50.0)	32/44 (72.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-int.sas:t-bimf-need-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.8692
Day 15			
Yes, n / N (%)	6/13 (46.2)	9/16 (56.3)	
No, n / N (%)	27/62 (43.5)	26/60 (43.3)	
Day 45			
Yes, n / N (%)	6/13 (46.2)	11/16 (68.8)	
No, n / N (%)	35/62 (56.5)	39/60 (65.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.4882(a) 0.9559(b) 0.3988(c)
Day 15			
<=24.9, n / N (%)	8/21 (38.1)	5/13 (38.5)	
25-29.9, n / N (%)	8/20 (40.0)	11/21 (52.4)	
>=30, n / N (%)	17/34 (50.0)	19/42 (45.2)	
Day 45			
<=24.9, n / N (%)	9/21 (42.9)	7/13 (53.8)	
25-29.9, n / N (%)	13/20 (65.0)	15/21 (71.4)	
>=30, n / N (%)	19/34 (55.9)	28/42 (66.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-int.sas:t-bimf-need-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.8924
Day 15			
3rd Trimester, n / N (%)	12/32 (37.5)	13/32 (40.6)	
Postpartum, n / N (%)	21/43 (48.8)	22/44 (50.0)	
Day 45			
3rd Trimester, n / N (%)	21/32 (65.6)	19/32 (59.4)	
Postpartum, n / N (%)	20/43 (46.5)	31/44 (70.5)	
Family History of PPD			0.7200
Day 15			
Yes, n / N (%)	5/10 (50.0)	4/10 (40.0)	
No/Unknown, n / N (%)	28/65 (43.1)	31/66 (47.0)	
Day 45			
Yes, n / N (%)	7/10 (70.0)	7/10 (70.0)	
No/Unknown, n / N (%)	34/65 (52.3)	43/66 (65.2)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-int.sas:t-bimf-need-resp15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.1251
Day 15			
1st Episode, n / N (%)	29/59 (49.2)	30/66 (45.5)	
Recurrent Episode, n / N (%)	4/16 (25.0)	5/10 (50.0)	
Day 45			
1st Episode, n / N (%)	35/59 (59.3)	43/66 (65.2)	
Recurrent Episode, n / N (%)	6/16 (37.5)	7/10 (70.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	6/8 (75.0)	4/10 (40.0)	
>=20, n / N (%)	27/67 (40.3)	31/66 (47.0)	
Day 45			
<20, n / N (%)	6/8 (75.0)	6/10 (60.0)	
>=20, n / N (%)	35/67 (52.2)	44/66 (66.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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3.3.2.1 .2 .2 Subgruppenanalysen

3.3.2.1 .2 .2 .1 Alter

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 3		
Number of subjects with a response, n (%) [2]	3 (12.0)	1 (5.9)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.489
95% CI for the RR		(0.056, 4.293)
p-value for RR		0.5184
Day 8		
Number of subjects with a response, n (%) [2]	11 (44.0)	7 (41.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.933
95% CI for the RR		(0.464, 1.876)
p-value for RR		0.8456

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 15		
Number of subjects with a response, n (%) [2]	10 (40.0)	8 (47.1)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.173
95% CI for the RR		(0.593, 2.321)
p-value for RR		0.6471
Day 21		
Number of subjects with a response, n (%) [2]	12 (48.0)	8 (47.1)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.977
95% CI for the RR		(0.512, 1.864)
p-value for RR		0.9446

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 45		
Number of subjects with a response, n (%) [2]	15 (60.0)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.977
95% CI for the RR		(0.581, 1.645)
p-value for RR		0.9313

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 3		
Number of subjects with a response, n (%) [2]	9 (18.0)	16 (27.1)
Number of subjects with missing evaluation, n (%)	3 (6.0)	3 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.514
95% CI for the RR		(0.748, 3.068)
p-value for RR		0.2492
Day 8		
Number of subjects with a response, n (%) [2]	22 (44.0)	24 (40.7)
Number of subjects with missing evaluation, n (%)	1 (2.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.929
95% CI for the RR		(0.610, 1.415)
p-value for RR		0.7326

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 15		
Number of subjects with a response, n (%) [2]	23 (46.0)	27 (45.8)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.000
95% CI for the RR		(0.666, 1.502)
p-value for RR		0.9998
Day 21		
Number of subjects with a response, n (%) [2]	28 (56.0)	24 (40.7)
Number of subjects with missing evaluation, n (%)	2 (4.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.730
95% CI for the RR		(0.499, 1.068)
p-value for RR		0.1054

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 45		
Number of subjects with a response, n (%) [2]	26 (52.0)	40 (67.8)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.311
95% CI for the RR		(0.959, 1.792)
p-value for RR		0.0899

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-age-itta.rtf **Run Date:** 24SEP2025

3.3.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 3		
Number of subjects with a response, n (%) [2]	3 (13.6)	7 (23.3)
Number of subjects with missing evaluation, n (%)	2 (9.1)	4 (13.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.583
95% CI for the RR		(0.457, 5.476)
p-value for RR		0.4684
Day 8		
Number of subjects with a response, n (%) [2]	14 (63.6)	12 (40.0)
Number of subjects with missing evaluation, n (%)	0	1 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.581
95% CI for the RR		(0.355, 0.951)
p-value for RR		0.0309

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 15		
Number of subjects with a response, n (%) [2]	12 (54.5)	14 (46.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.791
95% CI for the RR		(0.457, 1.372)
p-value for RR		0.4043
Day 21		
Number of subjects with a response, n (%) [2]	15 (68.2)	11 (36.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.497
95% CI for the RR		(0.297, 0.832)
p-value for RR		0.0078

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 45		
Number of subjects with a response, n (%) [2]	13 (59.1)	17 (56.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.887
95% CI for the RR		(0.557, 1.413)
p-value for RR		0.6140

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 3		
Number of subjects with a response, n (%) [2]	9 (17.0)	10 (21.7)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.296
95% CI for the RR		(0.586, 2.865)
p-value for RR		0.5224
Day 8		
Number of subjects with a response, n (%) [2]	19 (35.8)	19 (41.3)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.166
95% CI for the RR		(0.719, 1.891)
p-value for RR		0.5334

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 15		
Number of subjects with a response, n (%) [2]	21 (39.6)	21 (45.7)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.166
95% CI for the RR		(0.742, 1.833)
p-value for RR		0.5058
Day 21		
Number of subjects with a response, n (%) [2]	25 (47.2)	21 (45.7)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.979
95% CI for the RR		(0.646, 1.486)
p-value for RR		0.9222

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 45		
Number of subjects with a response, n (%) [2]	28 (52.8)	33 (71.7)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.374
95% CI for the RR		(1.007, 1.875)
p-value for RR		0.0448

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

3.3.2.1 .2 .2 .3 Abstammung

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 3		
Number of subjects with a response, n (%) [2]	5 (15.6)	3 (9.7)
Number of subjects with missing evaluation, n (%)	1 (3.1)	2 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.610
95% CI for the RR		(0.165, 2.259)
p-value for RR		0.4596
Day 8		
Number of subjects with a response, n (%) [2]	13 (40.6)	10 (32.3)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.782
95% CI for the RR		(0.416, 1.472)
p-value for RR		0.4468

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 2 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 15		
Number of subjects with a response, n (%) [2]	13 (40.6)	13 (41.9)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.017
95% CI for the RR		(0.568, 1.822)
p-value for RR		0.9543
Day 21		
Number of subjects with a response, n (%) [2]	14 (43.8)	12 (38.7)
Number of subjects with missing evaluation, n (%)	1 (3.1)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.872
95% CI for the RR		(0.489, 1.556)
p-value for RR		0.6426

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 45		
Number of subjects with a response, n (%) [2]	18 (56.3)	18 (58.1)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.017
95% CI for the RR		(0.665, 1.555)
p-value for RR		0.9372

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 3		
Number of subjects with a response, n (%) [2]	7 (17.5)	14 (31.8)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.800
95% CI for the RR		(0.823, 3.935)
p-value for RR		0.1409
Day 8		
Number of subjects with a response, n (%) [2]	18 (45.0)	21 (47.7)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.050
95% CI for the RR		(0.681, 1.619)
p-value for RR		0.8258

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	18 (45.0)	22 (50.0)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.100
95% CI for the RR		(0.707, 1.712)
p-value for RR		0.6732
Day 21		
Number of subjects with a response, n (%) [2]	24 (60.0)	20 (45.5)
Number of subjects with missing evaluation, n (%)	1 (2.5)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.750
95% CI for the RR		(0.512, 1.099)
p-value for RR		0.1397

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	20 (50.0)	32 (72.7)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.440
95% CI for the RR		(1.015, 2.042)
p-value for RR		0.0410

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-race-itta.rtf **Run Date:** 24SEP2025

3.3.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 6

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 3		
Number of subjects with a response, n (%) [2]	3 (23.1)	2 (12.5)
Number of subjects with missing evaluation, n (%)	0	2 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.591
95% CI for the RR		(0.111, 3.151)
p-value for RR		0.5379
Day 8		
Number of subjects with a response, n (%) [2]	7 (53.8)	8 (50.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.013
95% CI for the RR		(0.433, 2.370)
p-value for RR		0.9762

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 15		
Number of subjects with a response, n (%) [2]	6 (46.2)	9 (56.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.330
95% CI for the RR		(0.565, 3.127)
p-value for RR		0.5139
Day 21		
Number of subjects with a response, n (%) [2]	7 (53.8)	7 (43.8)
Number of subjects with missing evaluation, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.886
95% CI for the RR		(0.394, 1.995)
p-value for RR		0.7708

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 45		
Number of subjects with a response, n (%) [2]	6 (46.2)	11 (68.8)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.625
95% CI for the RR		(0.724, 3.650)
p-value for RR		0.2396

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 3		
Number of subjects with a response, n (%) [2]	9 (14.5)	15 (25.0)
Number of subjects with missing evaluation, n (%)	3 (4.8)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.671
95% CI for the RR		(0.803, 3.476)
p-value for RR		0.1698
Day 8		
Number of subjects with a response, n (%) [2]	26 (41.9)	23 (38.3)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.887
95% CI for the RR		(0.589, 1.336)
p-value for RR		0.5654

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 15		
Number of subjects with a response, n (%) [2]	27 (43.5)	26 (43.3)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.965
95% CI for the RR		(0.648, 1.439)
p-value for RR		0.8624
Day 21		
Number of subjects with a response, n (%) [2]	33 (53.2)	25 (41.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.759
95% CI for the RR		(0.527, 1.094)
p-value for RR		0.1398

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 45		
Number of subjects with a response, n (%) [2]	35 (56.5)	39 (65.0)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.117
95% CI for the RR		(0.841, 1.483)
p-value for RR		0.4444

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-adt-itta.rtf **Run Date:** 24SEP2025

3.3.2.1 .2 .2 .5 BMI

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 3		
Number of subjects with a response, n (%) [2]	5 (23.8)	2 (15.4)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.652
95% CI for the RR		(0.163, 2.606)
p-value for RR		0.5453
Day 8		
Number of subjects with a response, n (%) [2]	9 (42.9)	4 (30.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.725
95% CI for the RR		(0.294, 1.783)
p-value for RR		0.4831

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 15		
Number of subjects with a response, n (%) [2]	8 (38.1)	5 (38.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.019
95% CI for the RR		(0.454, 2.288)
p-value for RR		0.9638
Day 21		
Number of subjects with a response, n (%) [2]	8 (38.1)	6 (46.2)
Number of subjects with missing evaluation, n (%)	2 (9.5)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.223
95% CI for the RR		(0.593, 2.520)
p-value for RR		0.5859

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 45		
Number of subjects with a response, n (%) [2]	9 (42.9)	7 (53.8)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.268
95% CI for the RR		(0.674, 2.385)
p-value for RR		0.4613

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 3		
Number of subjects with a response, n (%) [2]	3 (15.0)	8 (38.1)
Number of subjects with missing evaluation, n (%)	1 (5.0)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.376
95% CI for the RR		(0.728, 7.756)
p-value for RR		0.1516
Day 8		
Number of subjects with a response, n (%) [2]	9 (45.0)	12 (57.1)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.188
95% CI for the RR		(0.654, 2.157)
p-value for RR		0.5710

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	8 (40.0)	11 (52.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.225
95% CI for the RR		(0.630, 2.383)
p-value for RR		0.5495
Day 21		
Number of subjects with a response, n (%) [2]	13 (65.0)	11 (52.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.754
95% CI for the RR		(0.455, 1.250)
p-value for RR		0.2738

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 45		
Number of subjects with a response, n (%) [2]	13 (65.0)	15 (71.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.028
95% CI for the RR		(0.687, 1.538)
p-value for RR		0.8923

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 3		
Number of subjects with a response, n (%) [2]	4 (11.8)	7 (16.7)
Number of subjects with missing evaluation, n (%)	1 (2.9)	3 (7.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.409
95% CI for the RR		(0.453, 4.386)
p-value for RR		0.5541
Day 8		
Number of subjects with a response, n (%) [2]	15 (44.1)	15 (35.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.805
95% CI for the RR		(0.470, 1.380)
p-value for RR		0.4301

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 15		
Number of subjects with a response, n (%) [2]	17 (50.0)	19 (45.2)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.900
95% CI for the RR		(0.562, 1.440)
p-value for RR		0.6598
Day 21		
Number of subjects with a response, n (%) [2]	19 (55.9)	15 (35.7)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.636
95% CI for the RR		(0.387, 1.044)
p-value for RR		0.0736

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 45		
Number of subjects with a response, n (%) [2]	19 (55.9)	28 (66.7)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.186
95% CI for the RR		(0.820, 1.717)
p-value for RR		0.3649

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

3.3.2.1 .2 .2 .6 Beginn der PPD

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 3		
Number of subjects with a response, n (%) [2]	4 (12.5)	8 (25.0)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.015
95% CI for the RR		(0.672, 6.041)
p-value for RR		0.2108
Day 8		
Number of subjects with a response, n (%) [2]	14 (43.8)	10 (31.3)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.720
95% CI for the RR		(0.373, 1.388)
p-value for RR		0.3266

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 15		
Number of subjects with a response, n (%) [2]	12 (37.5)	13 (40.6)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.092
95% CI for the RR		(0.586, 2.035)
p-value for RR		0.7824
Day 21		
Number of subjects with a response, n (%) [2]	17 (53.1)	11 (34.4)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.652
95% CI for the RR		(0.362, 1.174)
p-value for RR		0.1540

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 45		
Number of subjects with a response, n (%) [2]	21 (65.6)	19 (59.4)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.912
95% CI for the RR		(0.618, 1.346)
p-value for RR		0.6421

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 3		
Number of subjects with a response, n (%) [2]	8 (18.6)	9 (20.5)
Number of subjects with missing evaluation, n (%)	2 (4.7)	4 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.028
95% CI for the RR		(0.445, 2.374)
p-value for RR		0.9484
Day 8		
Number of subjects with a response, n (%) [2]	19 (44.2)	21 (47.7)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.010
95% CI for the RR		(0.661, 1.544)
p-value for RR		0.9634

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	21 (48.8)	22 (50.0)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.957
95% CI for the RR		(0.634, 1.446)
p-value for RR		0.8359
Day 21		
Number of subjects with a response, n (%) [2]	23 (53.5)	21 (47.7)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.834
95% CI for the RR		(0.557, 1.250)
p-value for RR		0.3802

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	20 (46.5)	31 (70.5)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.416
95% CI for the RR		(0.976, 2.055)
p-value for RR		0.0666

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-onset-itta.rtf **Run Date:** 24SEP2025

3.3.2.1 .2 .2 .7 PPD in der Familie

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 3		
Number of subjects with a response, n (%) [2]	2 (20.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.589
95% CI for the RR		(0.598, 11.199)
p-value for RR		0.2030
Day 8		
Number of subjects with a response, n (%) [2]	6 (60.0)	3 (30.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.647
95% CI for the RR		(0.210, 1.994)
p-value for RR		0.4486

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	5 (50.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.036
95% CI for the RR		(0.352, 3.049)
p-value for RR		0.9494
Day 21		
Number of subjects with a response, n (%) [2]	6 (60.0)	3 (30.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.647
95% CI for the RR		(0.206, 2.030)
p-value for RR		0.4557

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	7 (70.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.294
95% CI for the RR		(0.712, 2.353)
p-value for RR		0.3974

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 3		
Number of subjects with a response, n (%) [2]	10 (15.4)	13 (19.7)
Number of subjects with missing evaluation, n (%)	3 (4.6)	4 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.256
95% CI for the RR		(0.597, 2.641)
p-value for RR		0.5475
Day 8		
Number of subjects with a response, n (%) [2]	27 (41.5)	28 (42.4)
Number of subjects with missing evaluation, n (%)	1 (1.5)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.002
95% CI for the RR		(0.681, 1.475)
p-value for RR		0.9917

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	28 (43.1)	31 (47.0)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.070
95% CI for the RR		(0.736, 1.555)
p-value for RR		0.7238
Day 21		
Number of subjects with a response, n (%) [2]	34 (52.3)	29 (43.9)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.824
95% CI for the RR		(0.581, 1.169)
p-value for RR		0.2777

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	34 (52.3)	43 (65.2)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.222
95% CI for the RR		(0.915, 1.632)
p-value for RR		0.1741

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

3.3.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 3		
Number of subjects with a response, n (%) [2]	10 (16.9)	14 (21.2)
Number of subjects with missing evaluation, n (%)	1 (1.7)	4 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.200
95% CI for the RR		(0.586, 2.456)
p-value for RR		0.6185
Day 8		
Number of subjects with a response, n (%) [2]	29 (49.2)	26 (39.4)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.768
95% CI for the RR		(0.530, 1.114)
p-value for RR		0.1648

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 6

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	29 (49.2)	30 (45.5)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.886
95% CI for the RR		(0.615, 1.277)
p-value for RR		0.5177
Day 21		
Number of subjects with a response, n (%) [2]	33 (55.9)	27 (40.9)
Number of subjects with missing evaluation, n (%)	1 (1.7)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.701
95% CI for the RR		(0.494, 0.996)
p-value for RR		0.0474

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	35 (59.3)	43 (65.2)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.053
95% CI for the RR		(0.802, 1.382)
p-value for RR		0.7109

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 3		
Number of subjects with a response, n (%) [2]	2 (12.5)	3 (30.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.132
95% CI for the RR		(0.473, 20.716)
p-value for RR		0.2363
Day 8		
Number of subjects with a response, n (%) [2]	4 (25.0)	5 (50.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.610
95% CI for the RR		(0.675, 10.088)
p-value for RR		0.1644

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	4 (25.0)	5 (50.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.610
95% CI for the RR		(0.677, 10.056)
p-value for RR		0.1634
Day 21		
Number of subjects with a response, n (%) [2]	7 (43.8)	5 (50.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.491
95% CI for the RR		(0.463, 4.807)
p-value for RR		0.5034

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	6 (37.5)	7 (70.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.436
95% CI for the RR		(0.931, 6.370)
p-value for RR		0.0695

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response (6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline). Missing subscale score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

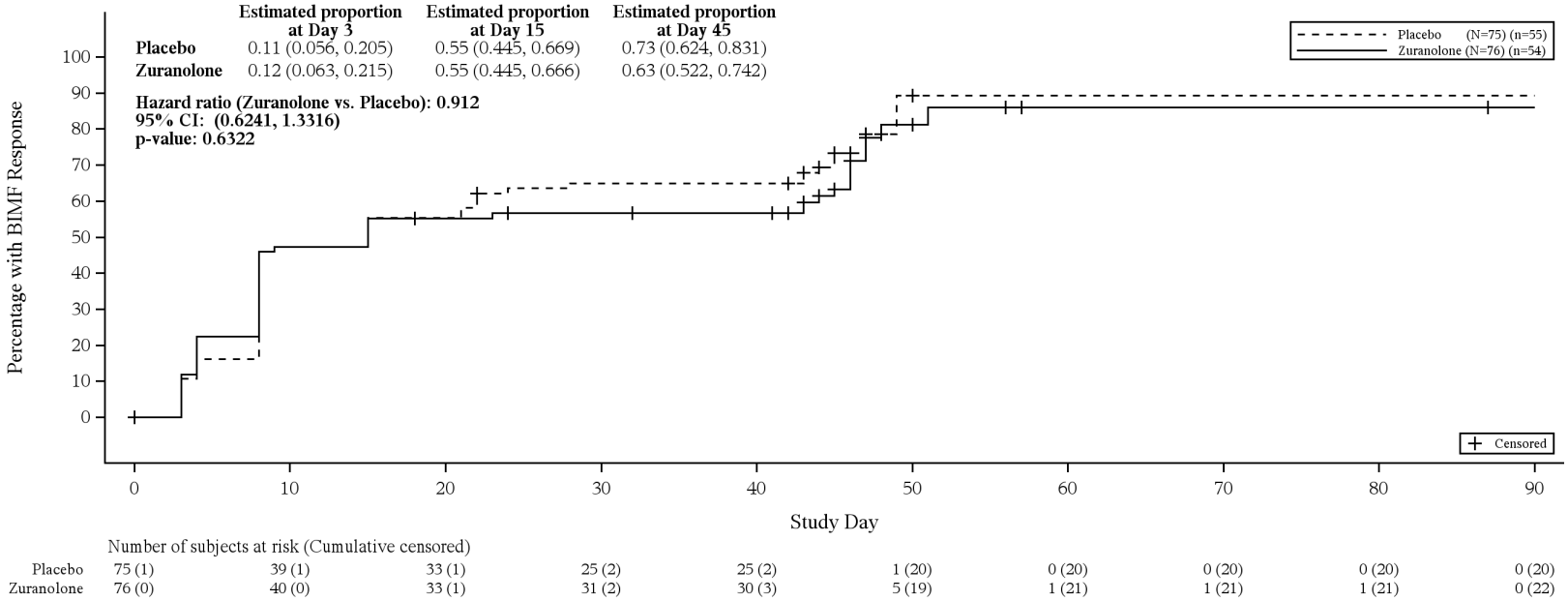
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-201-by.sas:t-bimf-need-resp15-201-by-hist-itta.rtf **Run Date:** 24SEP2025

3.3.2.2 TTE-Analysen

3.3.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-ovr.sas:f-bimf-need-resp15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	55 (73.3)	54 (71.1)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 22.0)	15.0 (8.0 , 44.0)
75th percentile - Q3 (95% CI)	47.0 (28.0, NE)	47.0 (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.912
95% CI for the HR		(0.6241 , 1.3316)
p-value for the HR		0.6322

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-ovr.sas:t-bimf-need-resp15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.3.2.2 .2 Subgruppen

3.3.2.2 .2 .1 Interaktionstest

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	55 (73.3)	54 (71.1)	
Age Group (years)			
18 - 24, n / N (%)	19/25 (76.0)	11/17 (64.7)	0.5604
25 - 45, n / N (%)	36/50 (72.0)	43/59 (72.9)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	16/22 (72.7)	20/30 (66.7)	0.6169
>=28, n / N (%)	39/53 (73.6)	34/46 (73.9)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	23/32 (71.9)	19/31 (61.3)	0.0573
White, n / N (%)	29/40 (72.5)	35/44 (79.5)	
Antidepressant Use at Baseline			
Yes, n / N (%)	9/13 (69.2)	12/16 (75.0)	0.7003
No, n / N (%)	46/62 (74.2)	42/60 (70.0)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-int.sas:t-bimf-need-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	12/21 (57.1)	8/13 (61.5)	0.9306(a)
25-29.9, n / N (%)	16/20 (80.0)	16/21 (76.2)	0.6535(b)
>=30, n / N (%)	27/34 (79.4)	30/42 (71.4)	0.5159(c)
Onset of PPD			
3rd Trimester, n / N (%)	27/32 (84.4)	19/32 (59.4)	0.0176
Postpartum, n / N (%)	28/43 (65.1)	35/44 (79.5)	
Family History of PPD			
Yes, n / N (%)	8/10 (80.0)	8/10 (80.0)	0.9344
No/Unknown, n / N (%)	47/65 (72.3)	46/66 (69.7)	
History of PPD			
1st Episode, n / N (%)	46/59 (78.0)	47/66 (71.2)	0.5099
Recurrent Episode, n / N (%)	9/16 (56.3)	7/10 (70.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	6/8 (75.0)	6/10 (60.0)	NA
>=20, n / N (%)	49/67 (73.1)	48/66 (72.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-int.sas:t-bimf-need-resp15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

3.3.2.2 .2 .2 Subgruppenanalysen

3.3.2.2 .2 .2 .1 Alter

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	19 (76.0)	11 (64.7)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 9.0)	8.0 (3.0 , 15.0)
50th percentile - median (95% CI)	21.0 (8.0 , 44.0)	15.0 (8.0 , 51.0)
75th percentile - Q3 (95% CI)	49.0 (24.0, NE)	51.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.715
95% CI for the HR		(0.3307 , 1.5440)
p-value for the HR		0.3926

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	36 (72.0)	43 (72.9)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 22.0)	15.0 (8.0 , 44.0)
75th percentile - Q3 (95% CI)	47.0 (22.0, NE)	47.0 (44.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.985
95% CI for the HR		(0.6317 , 1.5357)
p-value for the HR		0.9466

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-age-itta.rtf **Run Date:** 24SEP2025

3.3.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	16 (72.7)	20 (66.7)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 21.0)	15.0 (8.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (8.0, NE)	46.0 (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.852
95% CI for the HR		(0.4362 , 1.6649)
p-value for the HR		0.6396

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	39 (73.6)	34 (73.9)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	18.0 (8.0 , 43.0)	15.0 (8.0 , 45.0)
75th percentile - Q3 (95% CI)	47.0 (43.0, NE)	47.0 (44.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.958
95% CI for the HR		(0.6013 , 1.5278)
p-value for the HR		0.8585

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 24SEP2025

3.3.2.2 .2 .2 .3 Abstammung

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	23 (71.9)	19 (61.3)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	15.0 (8.0 , 43.0)	46.0 (8.0 , 47.0)
75th percentile - Q3 (95% CI)	47.0 (21.0, NE)	NE (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.655
95% CI for the HR		(0.3545 , 1.2103)
p-value for the HR		0.1768

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	29 (72.5)	35 (79.5)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 43.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	49.0 (24.0, NE)	47.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.294
95% CI for the HR		(0.7841 , 2.1369)
p-value for the HR		0.3129

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-race-itta.rtf **Run Date:** 24SEP2025

3.3.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	9 (69.2)	12 (75.0)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 9.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	9.0 (4.0, NE)	8.0 (8.0 , 47.0)
75th percentile - Q3 (95% CI)	NE (8.0, NE)	46.5 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.993
95% CI for the HR		(0.4150 , 2.3740)
p-value for the HR		0.9867

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	46 (74.2)	42 (70.0)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	6.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 22.0)	15.0 (8.0 , 45.0)
75th percentile - Q3 (95% CI)	47.0 (24.0, NE)	48.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.875
95% CI for the HR		(0.5727 , 1.3378)
p-value for the HR		0.5382

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-adt-itta.rtf **Run Date:** 24SEP2025

3.3.2.2 .2 .2 .5 BMI

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	12 (57.1)	8 (61.5)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	6.0 (3.0 , 8.0)	8.0 (3.0 , 43.0)
50th percentile - median (95% CI)	26.0 (4.0, NE)	43.0 (8.0, NE)
75th percentile - Q3 (95% CI)	49.0 (44.0, NE)	NE (23.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.156
95% CI for the HR		(0.4607 , 2.9022)
p-value for the HR		0.7571

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	16 (80.0)	16 (76.2)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	12.0 (8.0 , 43.0)	8.0 (4.0 , 46.0)
75th percentile - Q3 (95% CI)	44.0 (15.0, NE)	46.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.038
95% CI for the HR		(0.5123 , 2.1031)
p-value for the HR		0.9177

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	27 (79.4)	30 (71.4)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 22.0)	15.0 (8.0 , 46.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	48.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.739
95% CI for the HR		(0.4303 , 1.2679)
p-value for the HR		0.2718

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 24SEP2025

3.3.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	27 (84.4)	19 (59.4)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	6.0 (3.0 , 8.0)
50th percentile - median (95% CI)	9.0 (8.0 , 22.0)	46.0 (8.0 , 51.0)
75th percentile - Q3 (95% CI)	43.0 (15.0, NE)	NE (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.523
95% CI for the HR		(0.2803 , 0.9743)
p-value for the HR		0.0411

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	28 (65.1)	35 (79.5)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 49.0)	8.5 (8.0 , 23.0)
75th percentile - Q3 (95% CI)	49.0 (43.0, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.393
95% CI for the HR		(0.8339 , 2.3256)
p-value for the HR		0.2056

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-onset-itta.rtf **Run Date:** 24SEP2025

3.3.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	8 (80.0)	8 (80.0)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	3.0 (3.0 , 15.0)
50th percentile - median (95% CI)	8.0 (3.0 , 15.0)	11.5 (3.0, NE)
75th percentile - Q3 (95% CI)	15.0 (8.0, NE)	47.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.812
95% CI for the HR		(0.4069 , 8.0705)
p-value for the HR		0.4353

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	47 (72.3)	46 (69.7)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 28.0)	15.0 (8.0 , 45.0)
75th percentile - Q3 (95% CI)	47.0 (43.0, NE)	47.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.918
95% CI for the HR		(0.6092 , 1.3825)
p-value for the HR		0.6814

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 24SEP2025

3.3.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	46 (78.0)	47 (71.2)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	9.0 (8.0 , 22.0)	15.0 (8.0 , 44.0)
75th percentile - Q3 (95% CI)	45.0 (22.0, NE)	47.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.830
95% CI for the HR		(0.5503 , 1.2516)
p-value for the HR		0.3738

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-resp15-tte-201-by.sas:t-bimf-need-resp15-tte-201-by-hist-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	9 (56.3)	7 (70.0)
Time to first BIMF Mom's Needs Subscale response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 21.0)	4.0 (3.0 , 47.0)
50th percentile - median (95% CI)	22.0 (8.0, NE)	27.5 (3.0, NE)
75th percentile - Q3 (95% CI)	47.0 (22.0, NE)	48.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.961
95% CI for the HR		(0.3056 , 3.0228)
p-value for the HR		0.9458

NOTE 1: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

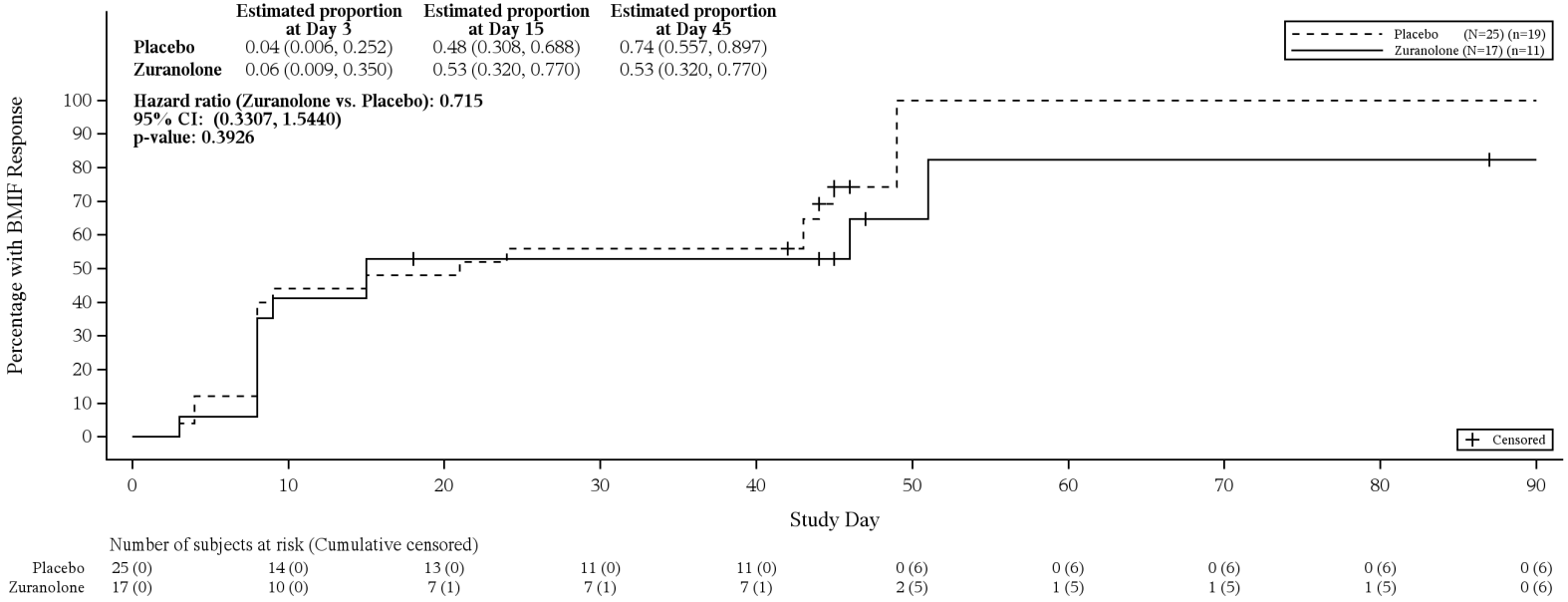
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3.3.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24

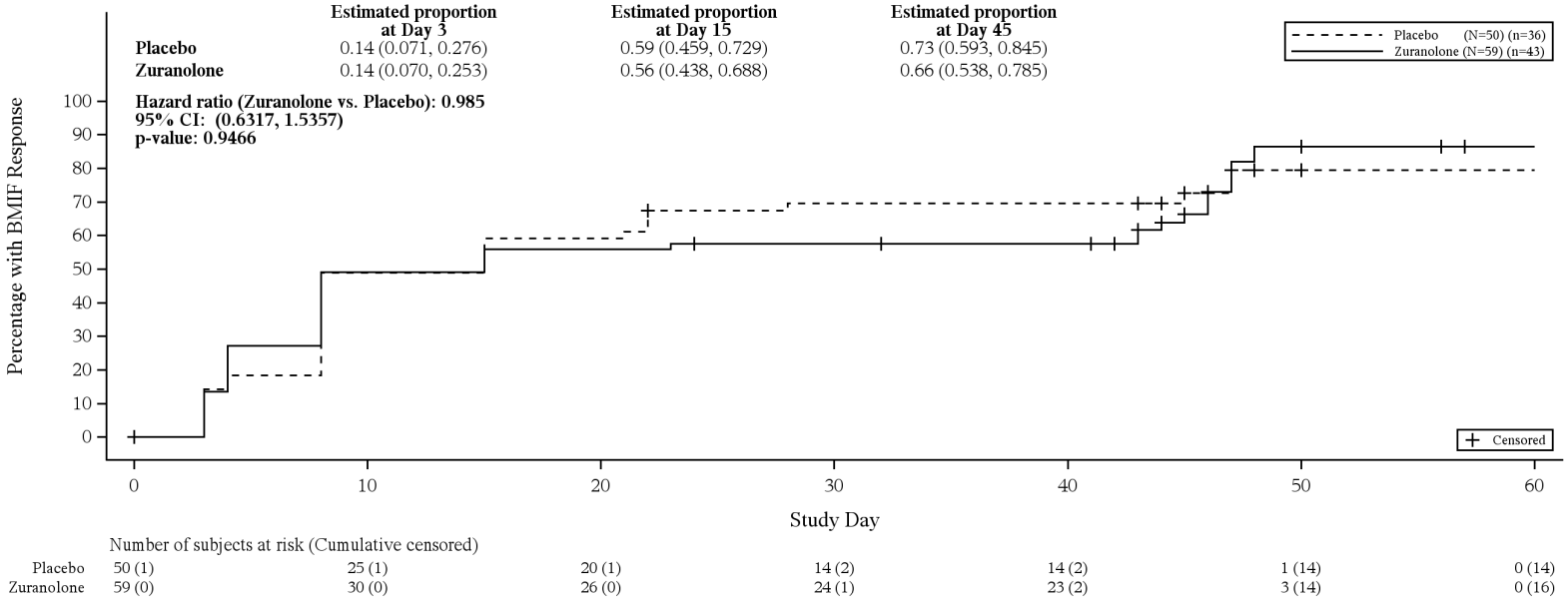


Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.
Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 25-45



Number of subjects at risk (Cumulative censored)

Placebo	50 (1)	25 (1)	20 (1)	14 (2)	14 (2)	1 (14)	0 (14)
Zuranolone	59 (0)	30 (0)	26 (0)	24 (1)	23 (2)	3 (14)	0 (16)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

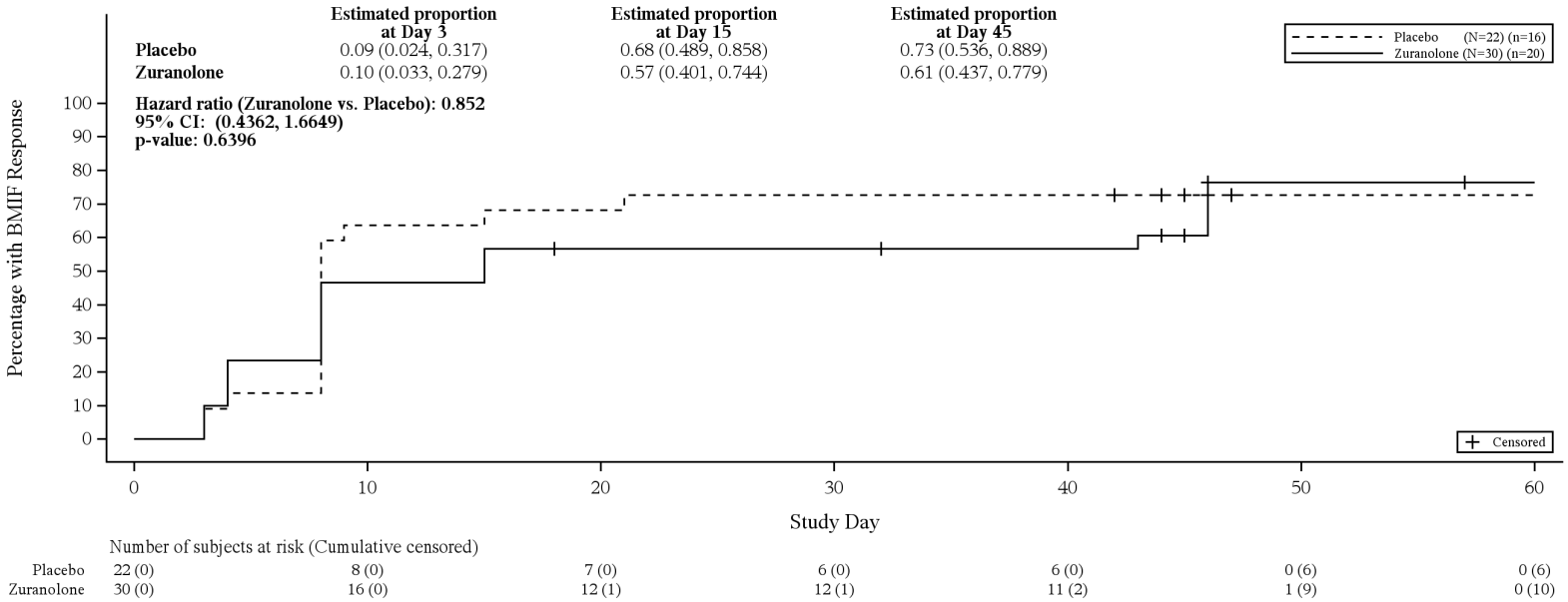
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	8 (0)	7 (0)	6 (0)	6 (0)	0 (6)	0 (6)
Zuranolone	30 (0)	16 (0)	12 (1)	12 (1)	11 (2)	1 (9)	0 (10)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

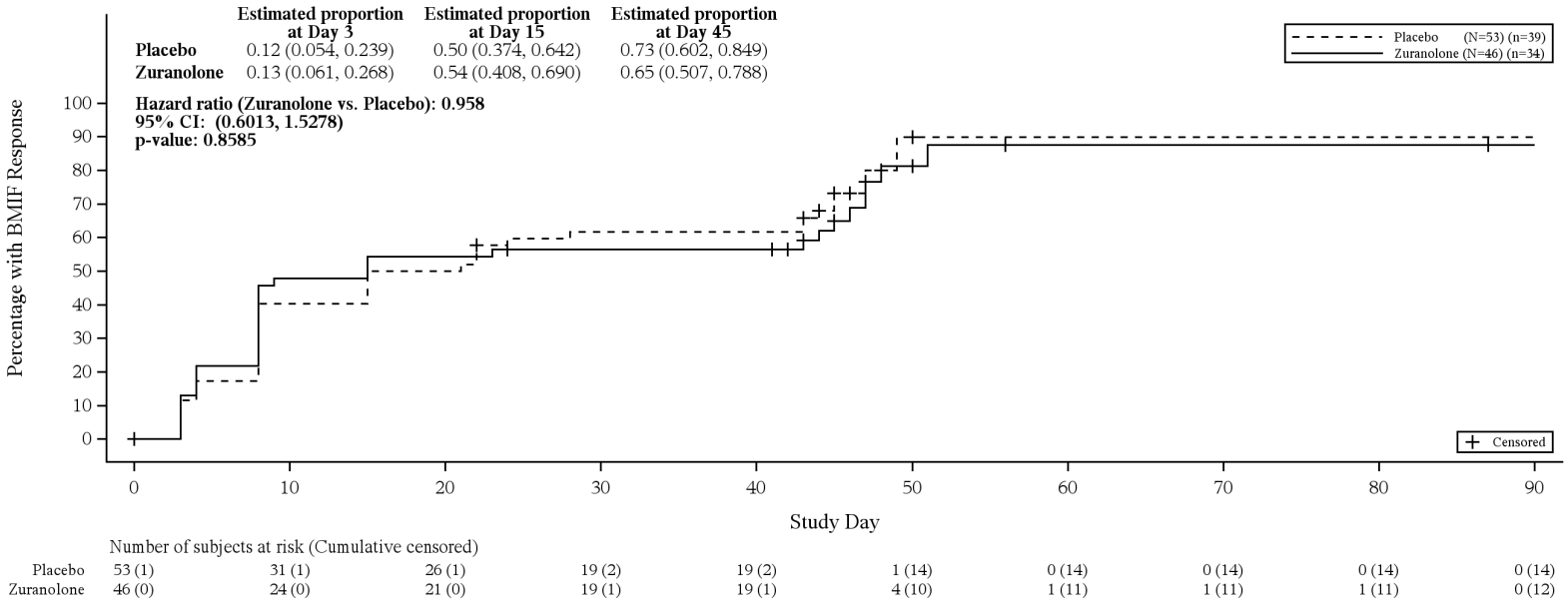
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

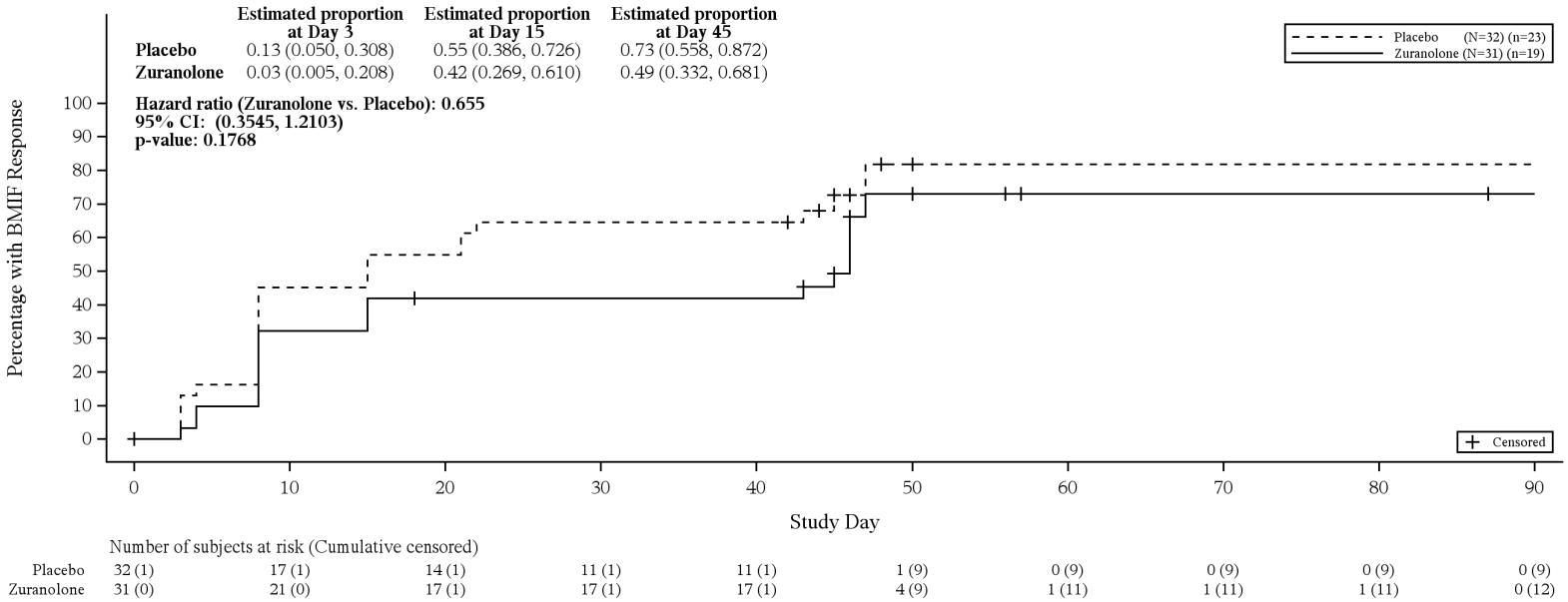
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

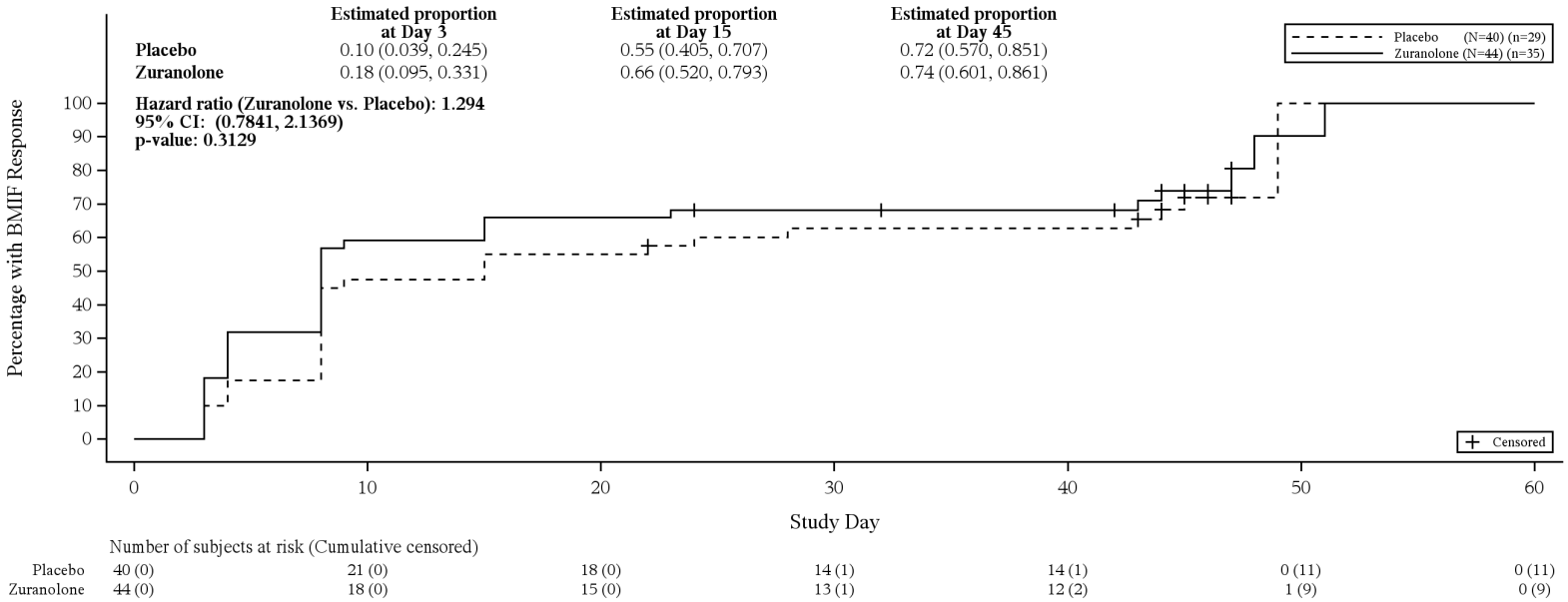
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

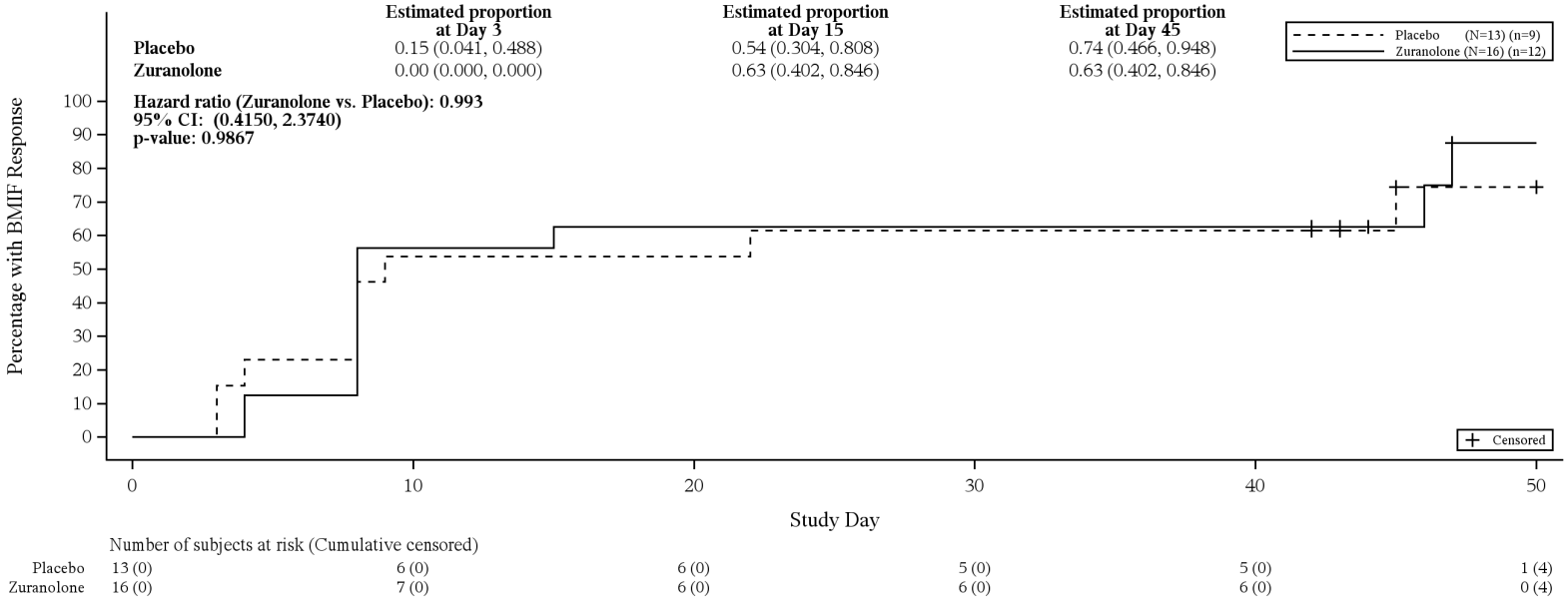
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

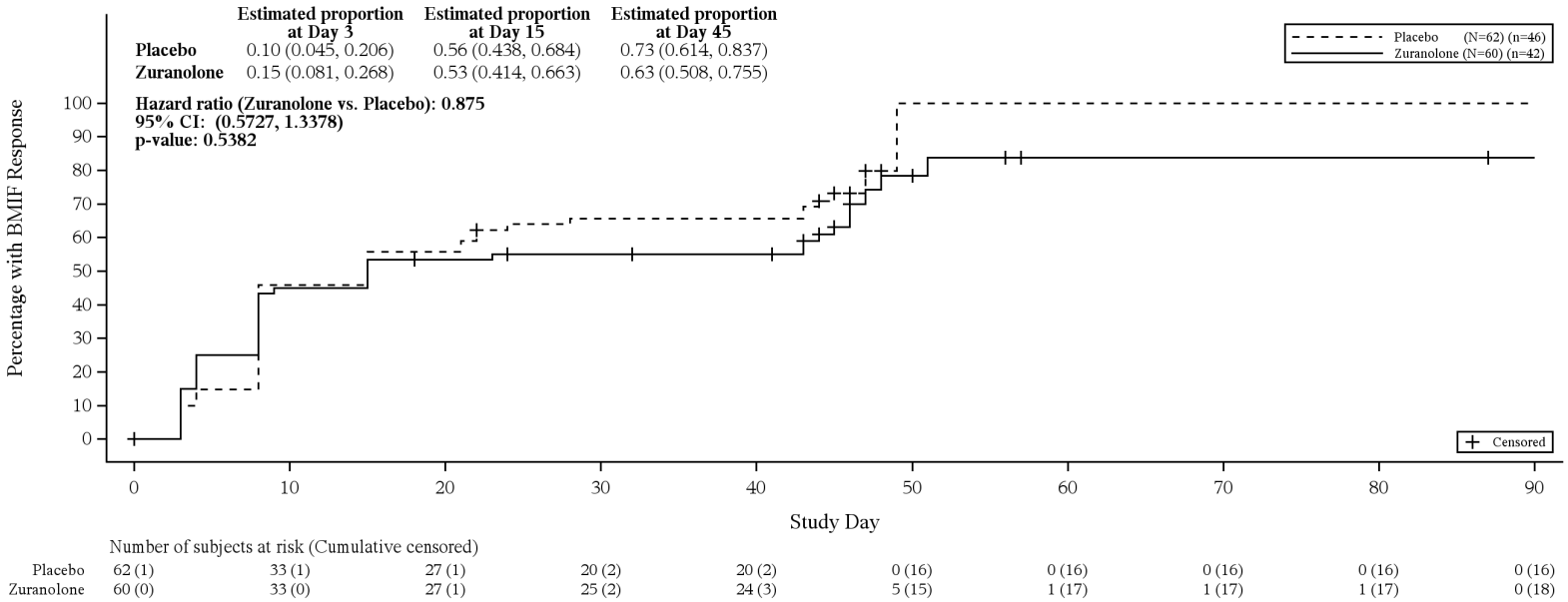
Placebo	13 (0)	6 (0)	6 (0)	5 (0)	5 (0)	1 (4)
Zuranolone	16 (0)	7 (0)	6 (0)	6 (0)	6 (0)	0 (4)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.
Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Number of subjects at risk (Cumulative censored)

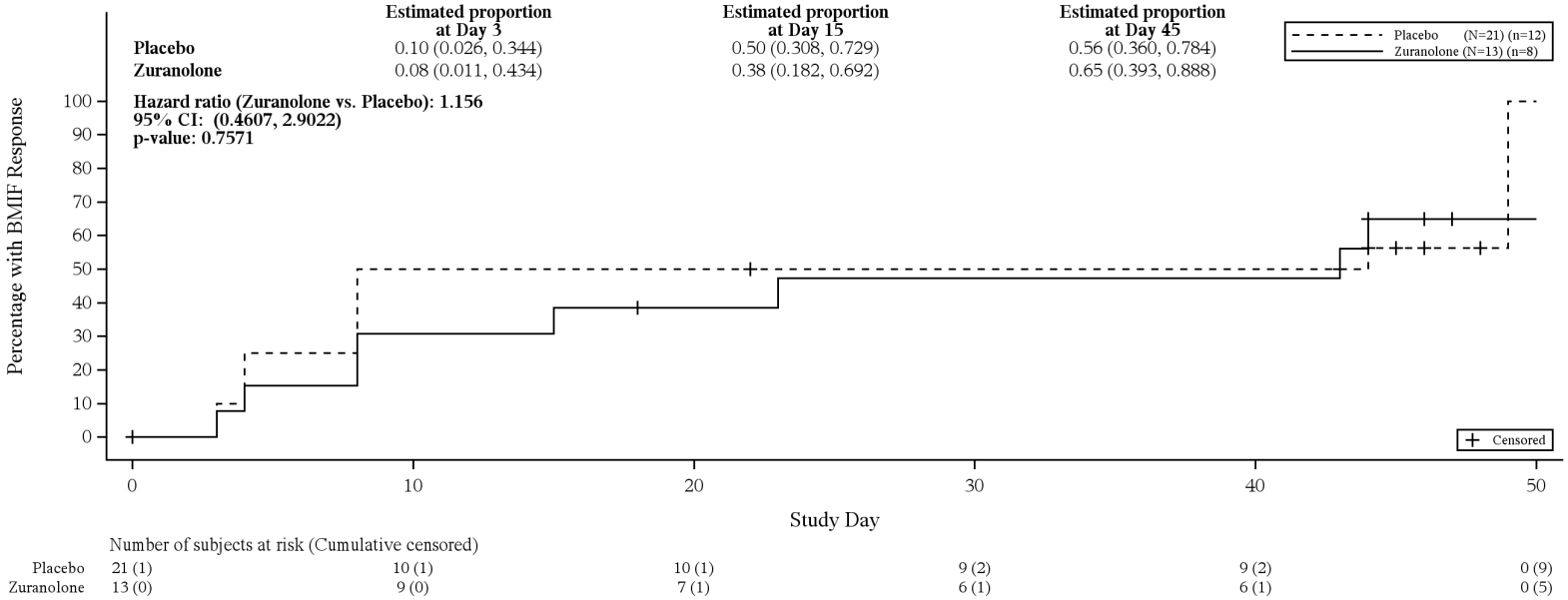
Placebo	62 (1)	33 (1)	27 (1)	20 (2)	20 (2)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)
Zuranolone	60 (0)	33 (0)	27 (1)	25 (2)	24 (3)	5 (15)	1 (17)	1 (17)	1 (17)	0 (18)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.
Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Number of subjects at risk (Cumulative censored)

Placebo	21 (1)	10 (1)	10 (1)	9 (2)	9 (2)	0 (9)
Zuranolone	13 (0)	9 (0)	7 (1)	6 (1)	6 (1)	0 (5)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

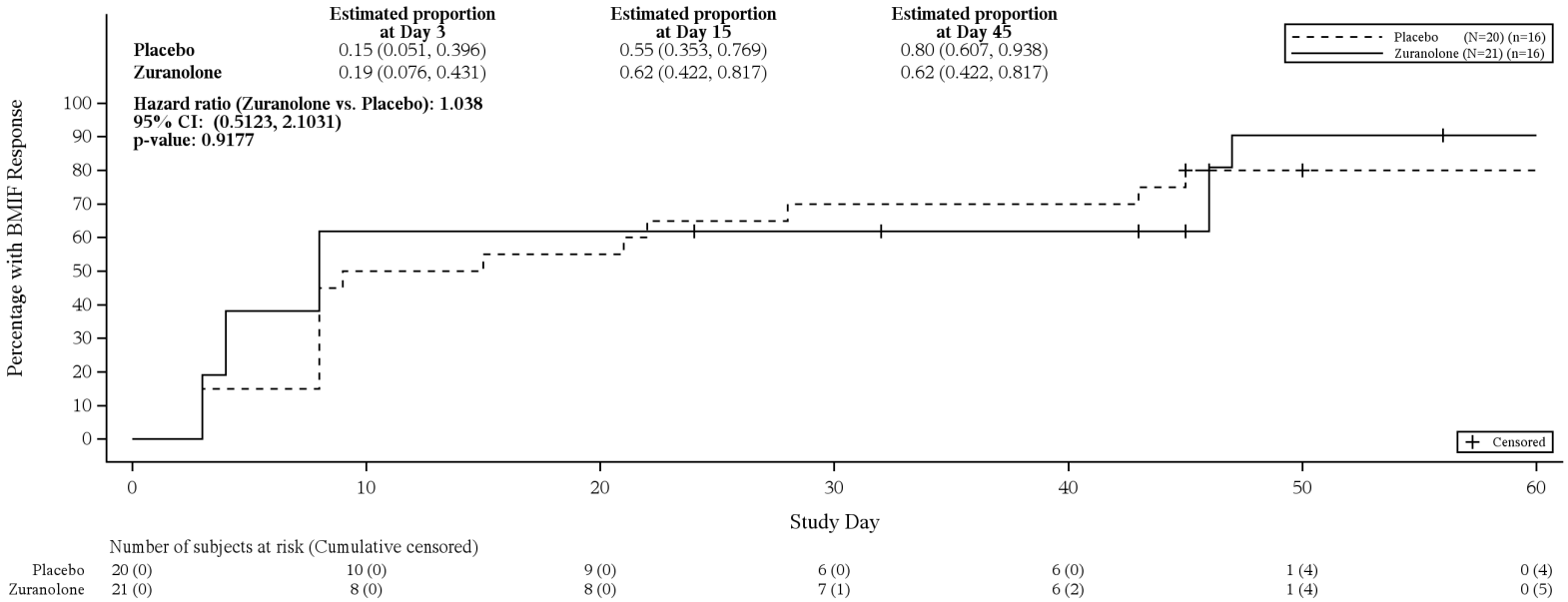
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

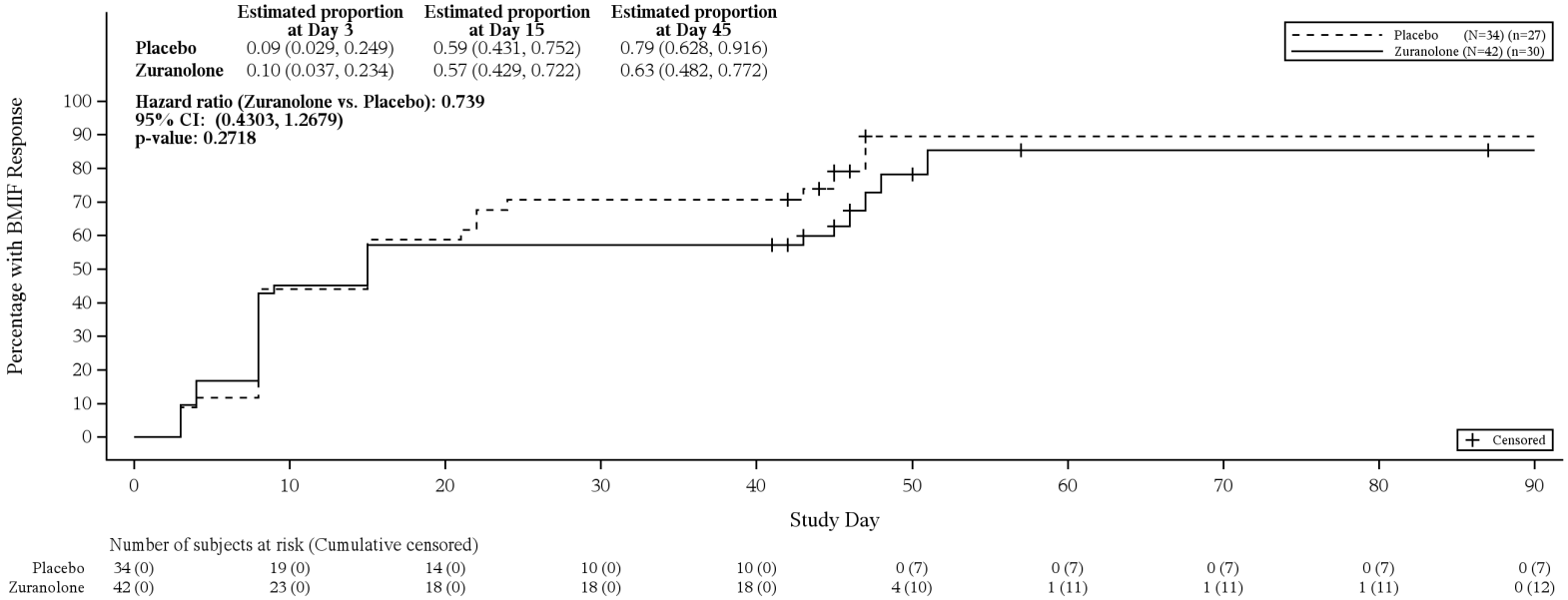
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

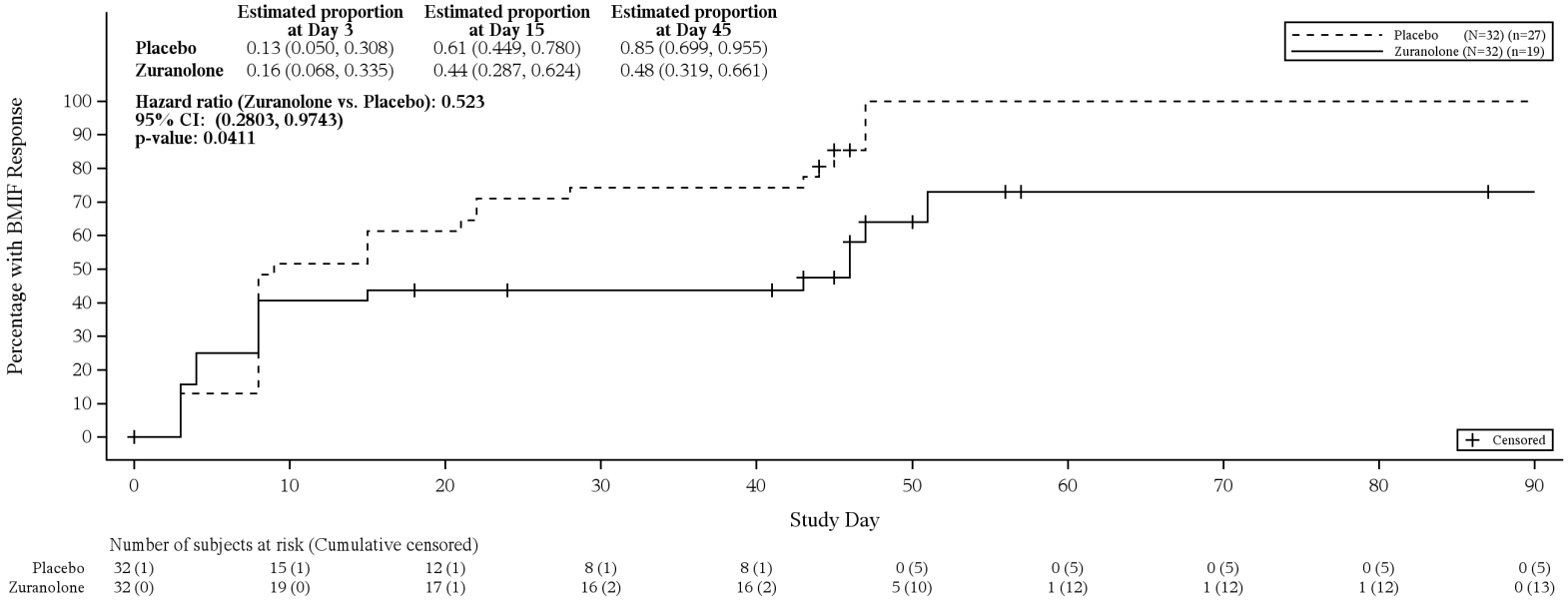
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

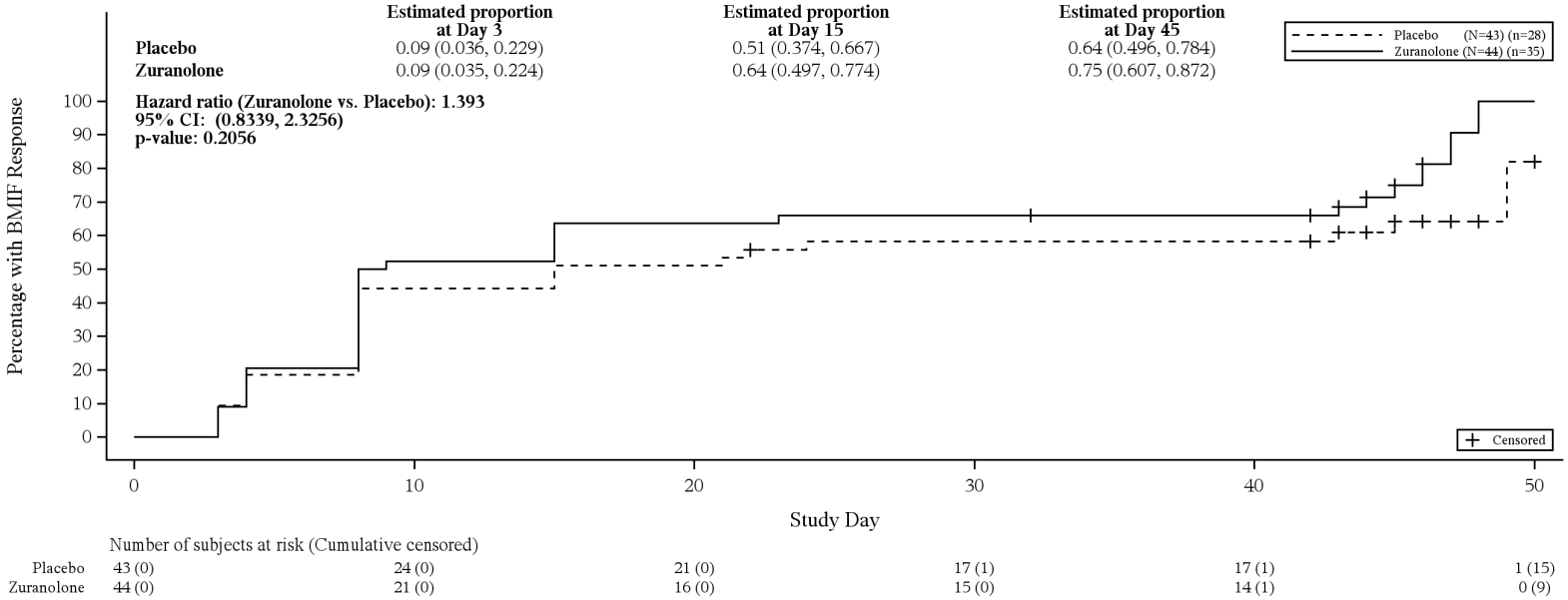
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Number of subjects at risk (Cumulative censored)

Placebo	43 (0)	24 (0)	21 (0)	17 (1)	17 (1)	1 (15)
Zuranolone	44 (0)	21 (0)	16 (0)	15 (0)	14 (1)	0 (9)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

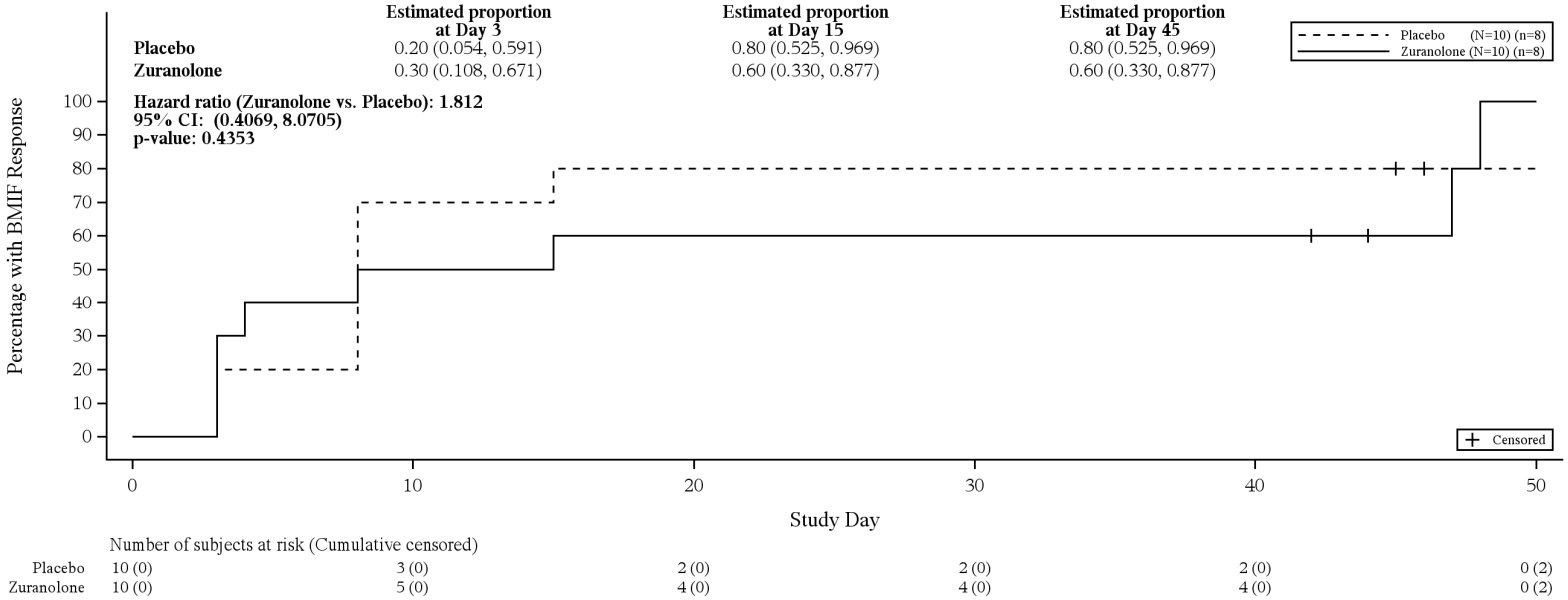
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Number of subjects at risk (Cumulative censored)

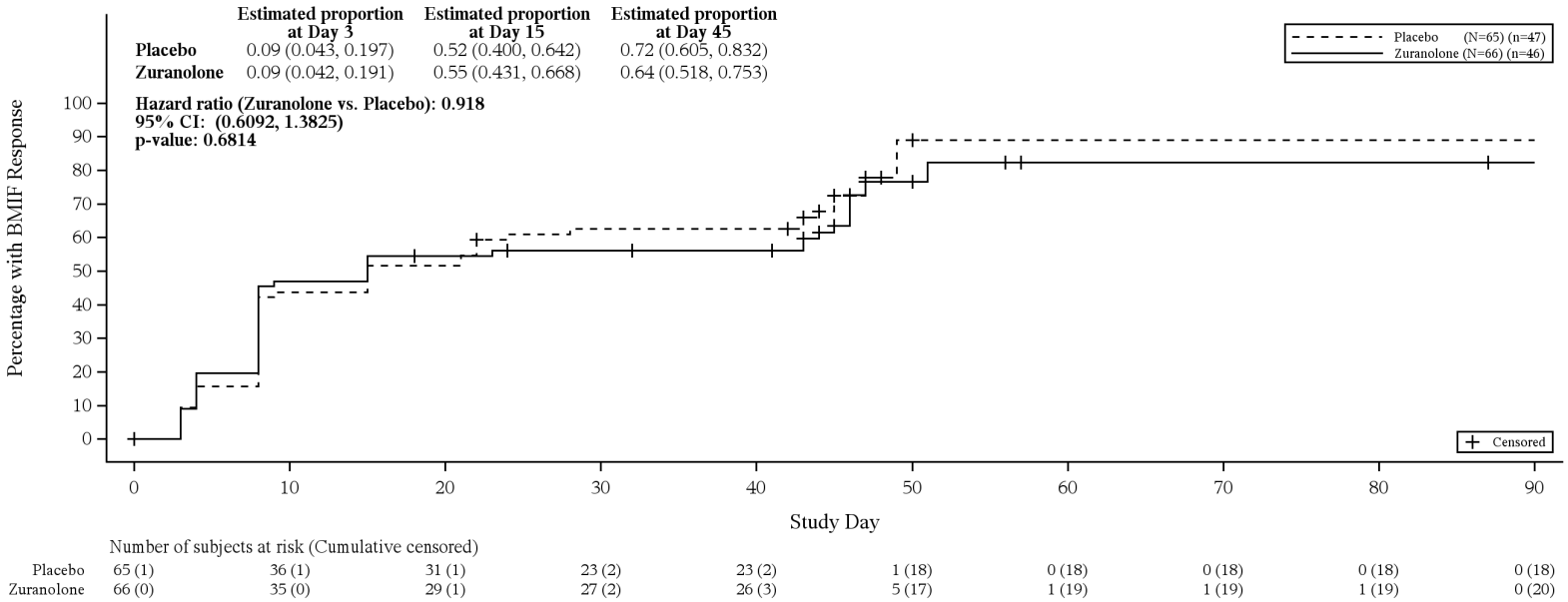
Placebo	10 (0)	3 (0)	2 (0)	2 (0)	2 (0)	0 (2)
Zuranolone	10 (0)	5 (0)	4 (0)	4 (0)	4 (0)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.
Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Number of subjects at risk (Cumulative censored)

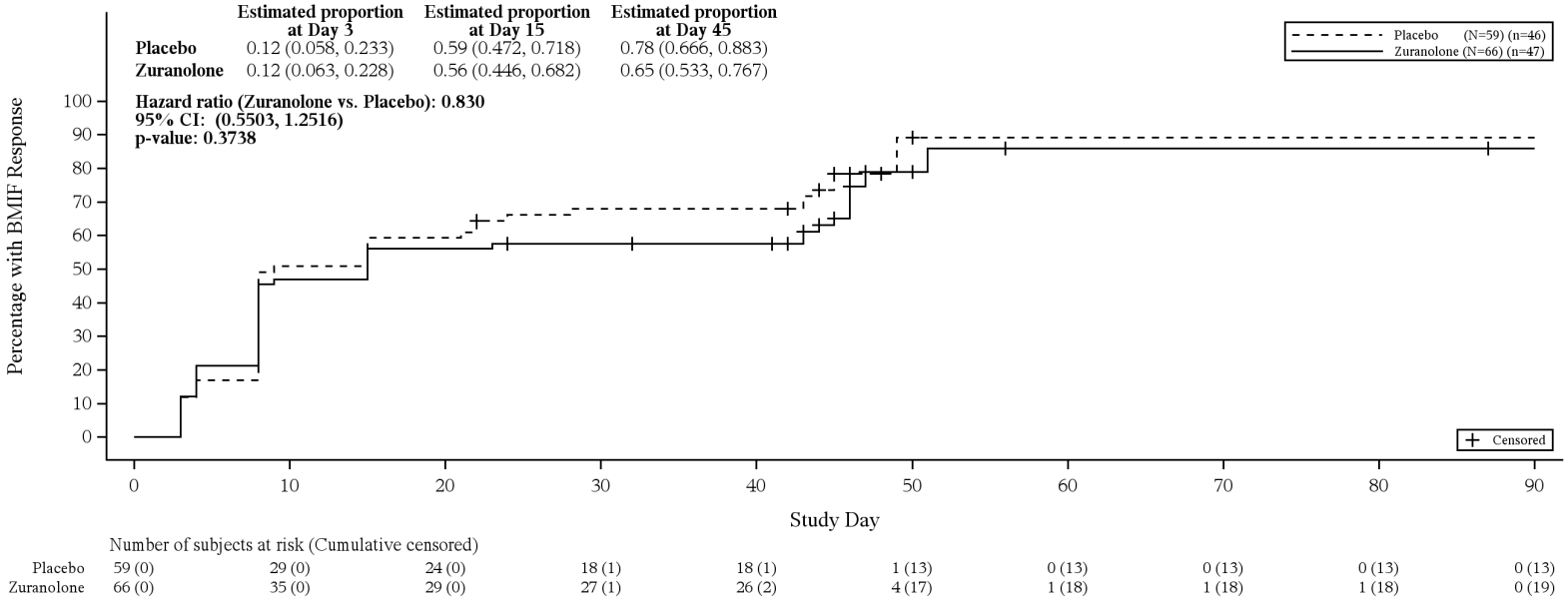
Placebo	65 (1)	36 (1)	31 (1)	23 (2)	23 (2)	1 (18)	0 (18)	0 (18)	0 (18)	0 (18)
Zuranolone	66 (0)	35 (0)	29 (1)	27 (2)	26 (3)	5 (17)	1 (19)	1 (19)	1 (19)	0 (20)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.
Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Number of subjects at risk (Cumulative censored)

Placebo	59 (0)	29 (0)	24 (0)	18 (1)	18 (1)	1 (13)	0 (13)	0 (13)	0 (13)	0 (13)
Zuranolone	66 (0)	35 (0)	29 (0)	27 (1)	26 (2)	4 (17)	1 (18)	1 (18)	1 (18)	0 (19)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

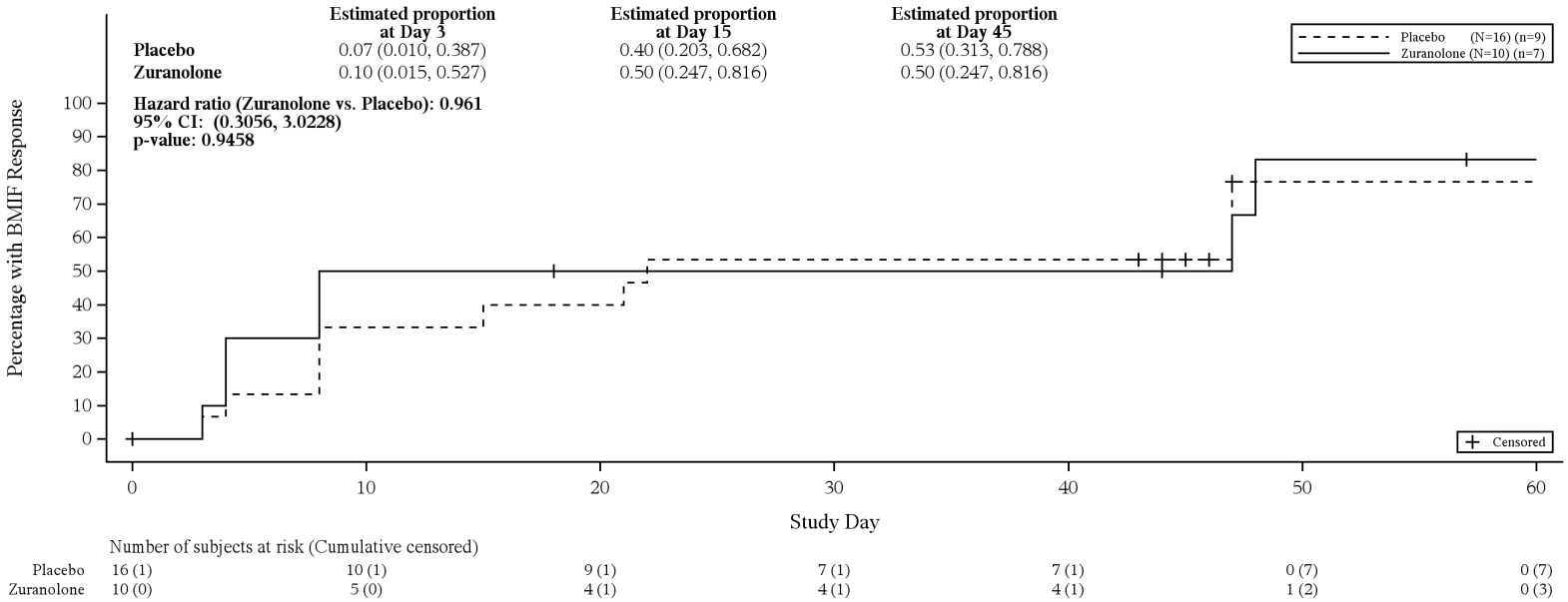
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Response (>=15% of total scale range increase from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Number of subjects at risk (Cumulative censored)

Placebo	16 (1)	10 (1)	9 (1)	7 (1)	7 (1)	0 (7)	0 (7)
Zuranolone	10 (0)	5 (0)	4 (1)	4 (1)	4 (1)	1 (2)	0 (3)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: BIMF Mom's needs subscale score response is defined as 6.3 points (15% of total scale range 0-42) or greater increase in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.
Source: biib125/v_a/amnog_kmplots/f-bimf-need-resp15-tte-201-by.sas:f-bimf-need-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

3.3.3 Verschlechterung

3.3.3.1 Responder-Analysen

3.3.3.1 .1 ITT-Population

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with worsening, n (%) [2]	4 (5.3)	3 (3.9)
Number of subjects with missing evaluation, n (%)	3 (4.0)	4 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.74
95% CI for the RR		(0.171, 3.195)
p-value for RR		0.6867
OR - Odds Ratio (Zuranolone vs. Placebo)		0.73
95% CI for the OR		(0.158, 3.376)
p-value for OR		0.6866
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.081, 0.053)
p-value for ARR		0.6856

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's needs subscale score worsening (6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-201-ovr.sas:t-bimf-need-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with worsening, n (%) [2]	0	1 (1.3)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.96
95% CI for the RR		(0.123, 71.552)
p-value for RR		0.5041
OR - Odds Ratio (Zuranolone vs. Placebo)		3.00
95% CI for the OR		(0.120, 74.819)
p-value for OR		0.5032
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.023, 0.049)
p-value for ARR		0.4803

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's needs subscale score worsening (6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-201-ovr.sas:t-bimf-need-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with worsening, n (%) [2]	1 (1.3)	3 (3.9)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		2.96
95% CI for the RR		(0.315, 27.825)
p-value for RR		0.3424
OR - Odds Ratio (Zuranolone vs. Placebo)		3.04
95% CI for the OR		(0.309, 29.915)
p-value for OR		0.3403
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.025, 0.077)
p-value for ARR		0.3141

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's needs subscale score worsening (6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-201-ovr.sas:t-bimf-need-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with worsening, n (%) [2]	1 (1.3)	3 (3.9)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		2.96
95% CI for the RR		(0.315, 27.825)
p-value for RR		0.3424
OR - Odds Ratio (Zuranolone vs. Placebo)		3.04
95% CI for the OR		(0.309, 29.915)
p-value for OR		0.3403
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.025, 0.077)
p-value for ARR		0.3141

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's needs subscale score worsening (6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-201-ovr.sas:t-bimf-need-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	1 (1.3)	0
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.014, 7.950)
p-value for RR		0.4939
OR - Odds Ratio (Zuranolone vs. Placebo)		0.32
95% CI for the OR		(0.013, 8.096)
p-value for OR		0.4930
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.049, 0.023)
p-value for ARR		0.4715

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a BIMF Mom's needs subscale score worsening (6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline). Missing subscale score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-201-ovr.sas:t-bimf-need-wors15-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.3.3.1 .2 Subgruppen

3.3.3.1 .2 .1 Interaktionstest

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	1 (1.3)	3 (3.9)	
Number of subjects with response at Day 45, n (%)	1 (1.3)	0	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	0/25	1/17 (5.9)	
25 - 45, n / N (%)	1/50 (2.0)	2/59 (3.4)	
Day 45			
18 - 24, n / N (%)	0/25	0/17	
25 - 45, n / N (%)	1/50 (2.0)	0/59	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score worsening is defined as 6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-201-int.sas:t-bimf-need-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	0/22	1/30 (3.3)	
>=28, n / N (%)	1/53 (1.9)	2/46 (4.3)	
Day 45			
<28, n / N (%)	1/22 (4.5)	0/30	
>=28, n / N (%)	0/53	0/46	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	1/32 (3.1)	1/31 (3.2)	
White, n / N (%)	0/40	2/44 (4.5)	
Day 45			
Black or African American, n / N (%)	1/32 (3.1)	0/31	
White, n / N (%)	0/40	0/44	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score worsening is defined as 6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-201-int.sas:t-bimf-need-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	1/62 (1.6)	3/60 (5.0)	
Day 45			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	1/62 (1.6)	0/60	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score worsening is defined as 6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-201-int.sas:t-bimf-need-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	0/21	1/13 (7.7)	
25-29.9, n / N (%)	0/20	1/21 (4.8)	
>=30, n / N (%)	1/34 (2.9)	1/42 (2.4)	
Day 45			
<=24.9, n / N (%)	0/21	0/13	
25-29.9, n / N (%)	0/20	0/21	
>=30, n / N (%)	1/34 (2.9)	0/42	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score worsening is defined as 6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-201-int.sas:t-bimf-need-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	0/32	2/32 (6.3)	
Postpartum, n / N (%)	1/43 (2.3)	1/44 (2.3)	
Day 45			
3rd Trimester, n / N (%)	1/32 (3.1)	0/32	
Postpartum, n / N (%)	0/43	0/44	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	1/65 (1.5)	3/66 (4.5)	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	1/65 (1.5)	0/66	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score worsening is defined as 6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-201-int.sas:t-bimf-need-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 6 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	0/59	3/66 (4.5)	
Recurrent Episode, n / N (%)	1/16 (6.3)	0/10	
Day 45			
1st Episode, n / N (%)	1/59 (1.7)	0/66	
Recurrent Episode, n / N (%)	0/16	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	1/67 (1.5)	3/66 (4.5)	
Day 45			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	1/67 (1.5)	0/66	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score worsening is defined as 6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-201-int.sas:t-bimf-need-wors15-201-int-itta.rtf **Run Date:** 24SEP2025

3.3.3.1 .2 .2 Subgruppenanalysen

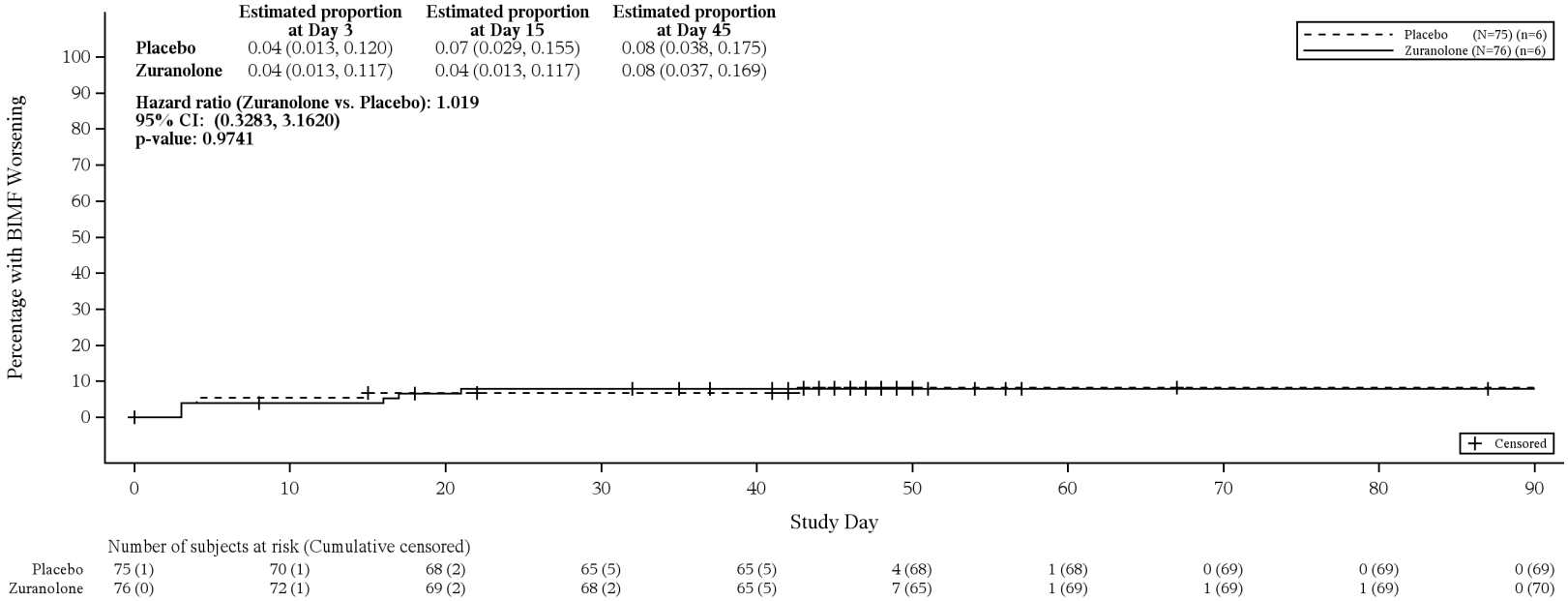
Nicht zutreffend.

3.3.3.2 TTE-Analysen

3.3.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing BIMF Mom's needs subscale score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: BIMF Mom's needs subscale score worsening is defined as 6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-bimf-need-wors15-tte-201-ovr.sas:f-bimf-need-wors15-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	6 (8.0)	6 (7.9)
Time to first BIMF Mom's Needs Subscale worsening (days) [3]		
25th percentile - Q1 (95% CI)	NE (NE, NE)	NE (NE, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.019
95% CI for the HR		(0.3283 , 3.1620)
p-value for the HR		0.9741

NOTE 1: BIMF Mom's needs subscale score worsening is defined as 6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing BIMF Mom's needs subscale score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a BIMF Mom's needs subscale score worsening. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline BIMF Mom's needs subscale score, and treatment.

Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-tte-201-ovr.sas:t-bimf-need-wors15-tte-201-ovr-itta.rtf **Run Date:** 24SEP2025

3.3.3.2 .2 Subgruppen

3.3.3.2 .2 .1 Interaktionstest

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	6 (8.0)	6 (7.9)	
Age Group (years)			
18 - 24, n / N (%)	1/25 (4.0)	1/17 (5.9)	NA
25 - 45, n / N (%)	5/50 (10.0)	5/59 (8.5)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	1/22 (4.5)	2/30 (6.7)	NA
>=28, n / N (%)	5/53 (9.4)	4/46 (8.7)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	4/32 (12.5)	3/31 (9.7)	NA
White, n / N (%)	2/40 (5.0)	3/44 (6.8)	
Antidepressant Use at Baseline			
Yes, n / N (%)	0/13	0/16	NA
No, n / N (%)	6/62 (9.7)	6/60 (10.0)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score worsening is defined as 6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-tte-201-int.sas:t-bimf-need-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

Summary of Time to First Barkin Index of Maternal Functioning (BIMF) Mom's Needs Subscale Worsening (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	1/21 (4.8)	3/13 (23.1)	NA(a)
25-29.9, n / N (%)	2/20 (10.0)	1/21 (4.8)	NA(b)
>=30, n / N (%)	3/34 (8.8)	2/42 (4.8)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	2/32 (6.3)	3/32 (9.4)	NA
Postpartum, n / N (%)	4/43 (9.3)	3/44 (6.8)	
Family History of PPD			
Yes, n / N (%)	0/10	0/10	NA
No/Unknown, n / N (%)	6/65 (9.2)	6/66 (9.1)	
History of PPD			
1st Episode, n / N (%)	5/59 (8.5)	6/66 (9.1)	NA
Recurrent Episode, n / N (%)	1/16 (6.3)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	1/8 (12.5)	0/10	NA
>=20, n / N (%)	5/67 (7.5)	6/66 (9.1)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: BIMF Mom's needs subscale score worsening is defined as 6.3 points (15% of total scale range 0-42) or greater reduction in subscale score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-bimf-need-wors15-tte-201-int.sas:t-bimf-need-wors15-tte-201-int-itta.rtf **Run Date:** 24SEP2025

3.3.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

3.3.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

4 Morbidität

4.1 HAMD-17

4.1.1 MMRM

Model-based Results on Change from Baseline in Hamilton Rating Scale for Depression (HAMD-17) Total Score: 217-PPD-201B - ITT population

Page: 1 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 3		
n	74	74
LS Mean (SE)	-9.73 (0.844)	-12.43 (0.840)
95% CI for the LS Mean	-11.40, -8.06	-14.09, -10.77
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.70 (1.193)
95% CI for the LS Mean		-5.06, -0.34
p-value		0.0252
Hedges' g (Zuranolone vs. Placebo)		-0.370
95% CI for Hedges' g		-0.6950, -0.0451
Day 8		
n	74	75
LS Mean (SE)	-12.87 (0.930)	-16.26 (0.922)
95% CI for the LS Mean	-14.70, -11.03	-18.08, -14.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.40 (1.312)
95% CI for the LS Mean		-5.99, -0.80
p-value		0.0106
Hedges' g (Zuranolone vs. Placebo)		-0.422
95% CI for Hedges' g		-0.7467, -0.0973

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The HAMD-17 total score was calculated as the sum of the 17 individual item scores. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-hamd-mmrm-201-ovr.sas:t-hamd-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Hamilton Rating Scale for Depression (HAMD-17) Total Score: 217-PPD-201B - ITT population

Page: 2 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	-13.55 (0.975)	-17.72 (0.965)
95% CI for the LS Mean	-15.48, -11.63	-19.63, -15.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.17 (1.374)
95% CI for the LS Mean		-6.89, -1.46
p-value		0.0028
Hedges' g (Zuranolone vs. Placebo)		-0.498
95% CI for Hedges' g		-0.8267, -0.1701
Day 21		
n	73	74
LS Mean (SE)	-14.41 (1.020)	-17.53 (1.011)
95% CI for the LS Mean	-16.43, -12.40	-19.53, -15.53
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.11 (1.438)
95% CI for the LS Mean		-5.96, -0.27
p-value		0.0321
Hedges' g (Zuranolone vs. Placebo)		-0.355
95% CI for Hedges' g		-0.6811, -0.0294

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The HAMD-17 total score was calculated as the sum of the 17 individual item scores. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-hamd-mmrm-201-ovr.sas:t-hamd-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Hamilton Rating Scale for Depression (HAMD-17) Total Score: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 45		
n	69	73
LS Mean (SE)	-15.03 (0.956)	-19.12 (0.937)
95% CI for the LS Mean	-16.92, -13.14	-20.98, -17.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.09 (1.341)
95% CI for the LS Mean		-6.74, -1.44
p-value		0.0027
Hedges' g (Zuranolone vs. Placebo)		-0.510
95% CI for Hedges' g		-0.8445, -0.1757

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The HAMD-17 total score was calculated as the sum of the 17 individual item scores. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-hamd-mmrm-201-ovr.sas:t-hamd-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.1.2 Ansprechen

4.1.2.1 Responder-Analysen

4.1.2.1 .1 ITT-Population

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with a response, n (%) [2]	20 (26.7)	30 (39.5)
Number of subjects with missing evaluation, n (%)	1 (1.3)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.525
95% CI for the RR		(0.956, 2.431)
p-value for RR		0.0766
OR - Odds Ratio (Zuranolone vs. Placebo)		1.818
95% CI for the OR		(0.911, 3.628)
p-value for OR		0.0900
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.132
95% CI for the ARR		(-0.017, 0.282)
p-value for ARR		0.0822

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-ovr.sas:t-hamd-resp50-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

Page: 2 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with a response, n (%) [2]	33 (44.0)	49 (64.5)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.525
95% CI for the RR		(1.129, 2.061)
p-value for RR		0.0060
OR - Odds Ratio (Zuranolone vs. Placebo)		2.357
95% CI for the OR		(1.227, 4.531)
p-value for OR		0.0101
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.213
95% CI for the ARR		(0.059, 0.368)
p-value for ARR		0.0068

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-ovr.sas:t-hamd-resp50-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

Page: 3 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with a response, n (%) [2]	35 (46.7)	53 (69.7)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.539
95% CI for the RR		(1.160, 2.043)
p-value for RR		0.0028
OR - Odds Ratio (Zuranolone vs. Placebo)		2.693
95% CI for the OR		(1.381, 5.249)
p-value for OR		0.0036
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.238
95% CI for the ARR		(0.085, 0.390)
p-value for ARR		0.0023

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-ovr.sas:t-hamd-resp50-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

Page: 4 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with a response, n (%) [2]	41 (54.7)	53 (69.7)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.335
95% CI for the RR		(1.036, 1.719)
p-value for RR		0.0253
OR - Odds Ratio (Zuranolone vs. Placebo)		1.955
95% CI for the OR		(1.003, 3.809)
p-value for OR		0.0489
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.160
95% CI for the ARR		(0.008, 0.312)
p-value for ARR		0.0397

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-ovr.sas:t-hamd-resp50-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	39 (52.0)	55 (72.4)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.426
95% CI for the RR		(1.103, 1.843)
p-value for RR		0.0068
OR - Odds Ratio (Zuranolone vs. Placebo)		2.474
95% CI for the OR		(1.256, 4.875)
p-value for OR		0.0088
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.210
95% CI for the ARR		(0.059, 0.361)
p-value for ARR		0.0063

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-ovr.sas:t-hamd-resp50-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.1.2.1 .2 Subgruppen

4.1.2.1 .2 .1 Interaktionstest

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	35 (46.7)	53 (69.7)	
Number of subjects with response at Day 45, n (%)	39 (52.0)	55 (72.4)	
Age Group (years)			0.5600
Day 15			
18 - 24, n / N (%)	10/25 (40.0)	10/17 (58.8)	
25 - 45, n / N (%)	25/50 (50.0)	43/59 (72.9)	
Day 45			
18 - 24, n / N (%)	14/25 (56.0)	10/17 (58.8)	
25 - 45, n / N (%)	25/50 (50.0)	45/59 (76.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-int.sas:t-hamd-resp50-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.0758
Day 15			
<28, n / N (%)	12/22 (54.5)	18/30 (60.0)	
>=28, n / N (%)	23/53 (43.4)	35/46 (76.1)	
Day 45			
<28, n / N (%)	13/22 (59.1)	21/30 (70.0)	
>=28, n / N (%)	26/53 (49.1)	34/46 (73.9)	
Race Group (Black or African American, White)			0.9117
Day 15			
Black or African American, n / N (%)	14/32 (43.8)	21/31 (67.7)	
White, n / N (%)	19/40 (47.5)	31/44 (70.5)	
Day 45			
Black or African American, n / N (%)	17/32 (53.1)	21/31 (67.7)	
White, n / N (%)	21/40 (52.5)	33/44 (75.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-int.sas:t-hamd-resp50-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.8122
Day 15			
Yes, n / N (%)	6/13 (46.2)	11/16 (68.8)	
No, n / N (%)	29/62 (46.8)	42/60 (70.0)	
Day 45			
Yes, n / N (%)	6/13 (46.2)	12/16 (75.0)	
No, n / N (%)	33/62 (53.2)	43/60 (71.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-int.sas:t-hamd-resp50-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.0396(a) 0.4488(b) 0.0008(c)
Day 15			
<=24.9, n / N (%)	8/21 (38.1)	8/13 (61.5)	
25-29.9, n / N (%)	7/20 (35.0)	18/21 (85.7)	
>=30, n / N (%)	20/34 (58.8)	27/42 (64.3)	
Day 45			
<=24.9, n / N (%)	10/21 (47.6)	10/13 (76.9)	
25-29.9, n / N (%)	10/20 (50.0)	19/21 (90.5)	
>=30, n / N (%)	19/34 (55.9)	26/42 (61.9)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-int.sas:t-hamd-resp50-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.8384
Day 15			
3rd Trimester, n / N (%)	14/32 (43.8)	23/32 (71.9)	
Postpartum, n / N (%)	21/43 (48.8)	30/44 (68.2)	
Day 45			
3rd Trimester, n / N (%)	18/32 (56.3)	25/32 (78.1)	
Postpartum, n / N (%)	21/43 (48.8)	30/44 (68.2)	
Family History of PPD			0.5334
Day 15			
Yes, n / N (%)	4/10 (40.0)	7/10 (70.0)	
No/Unknown, n / N (%)	31/65 (47.7)	46/66 (69.7)	
Day 45			
Yes, n / N (%)	6/10 (60.0)	6/10 (60.0)	
No/Unknown, n / N (%)	33/65 (50.8)	49/66 (74.2)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.3126
Day 15			
1st Episode, n / N (%)	30/59 (50.8)	48/66 (72.7)	
Recurrent Episode, n / N (%)	5/16 (31.3)	5/10 (50.0)	
Day 45			
1st Episode, n / N (%)	33/59 (55.9)	49/66 (74.2)	
Recurrent Episode, n / N (%)	6/16 (37.5)	6/10 (60.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	5/8 (62.5)	7/10 (70.0)	
>=20, n / N (%)	30/67 (44.8)	46/66 (69.7)	
Day 45			
<20, n / N (%)	6/8 (75.0)	8/10 (80.0)	
>=20, n / N (%)	33/67 (49.3)	47/66 (71.2)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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4.1.2.1 .2 .2 Subgruppenanalysen

4.1.2.1 .2 .2 .1 Alter

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 3		
Number of subjects with a response, n (%) [2]	9 (36.0)	8 (47.1)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.362
95% CI for the RR		(0.671, 2.764)
p-value for RR		0.3928
Day 8		
Number of subjects with a response, n (%) [2]	11 (44.0)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.532
95% CI for the RR		(0.879, 2.668)
p-value for RR		0.1320

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

Page: 2 of 6

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 15		
Number of subjects with a response, n (%) [2]	10 (40.0)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.532
95% CI for the RR		(0.833, 2.817)
p-value for RR		0.1700
Day 21		
Number of subjects with a response, n (%) [2]	15 (60.0)	12 (70.6)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.225
95% CI for the RR		(0.787, 1.909)
p-value for RR		0.3687

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 45		
Number of subjects with a response, n (%) [2]	14 (56.0)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.094
95% CI for the RR		(0.649, 1.845)
p-value for RR		0.7359

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 3		
Number of subjects with a response, n (%) [2]	11 (22.0)	22 (37.3)
Number of subjects with missing evaluation, n (%)	1 (2.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.691
95% CI for the RR		(0.912, 3.133)
p-value for RR		0.0952
Day 8		
Number of subjects with a response, n (%) [2]	22 (44.0)	38 (64.4)
Number of subjects with missing evaluation, n (%)	1 (2.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.460
95% CI for the RR		(1.013, 2.104)
p-value for RR		0.0423

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 15		
Number of subjects with a response, n (%) [2]	25 (50.0)	43 (72.9)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.454
95% CI for the RR		(1.060, 1.995)
p-value for RR		0.0204
Day 21		
Number of subjects with a response, n (%) [2]	26 (52.0)	41 (69.5)
Number of subjects with missing evaluation, n (%)	2 (4.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.333
95% CI for the RR		(0.974, 1.825)
p-value for RR		0.0729

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 45		
Number of subjects with a response, n (%) [2]	25 (50.0)	45 (76.3)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.522
95% CI for the RR		(1.115, 2.077)
p-value for RR		0.0082

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.1.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 3		
Number of subjects with a response, n (%) [2]	7 (31.8)	9 (30.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.946
95% CI for the RR		(0.416, 2.153)
p-value for RR		0.8949
Day 8		
Number of subjects with a response, n (%) [2]	9 (40.9)	16 (53.3)
Number of subjects with missing evaluation, n (%)	0	1 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.308
95% CI for the RR		(0.717, 2.387)
p-value for RR		0.3813

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 15		
Number of subjects with a response, n (%) [2]	12 (54.5)	18 (60.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.104
95% CI for the RR		(0.681, 1.788)
p-value for RR		0.6884
Day 21		
Number of subjects with a response, n (%) [2]	15 (68.2)	16 (53.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.785
95% CI for the RR		(0.507, 1.215)
p-value for RR		0.2770

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 45		
Number of subjects with a response, n (%) [2]	13 (59.1)	21 (70.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.189
95% CI for the RR		(0.783, 1.804)
p-value for RR		0.4168

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 3		
Number of subjects with a response, n (%) [2]	13 (24.5)	21 (45.7)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.863
95% CI for the RR		(1.054, 3.292)
p-value for RR		0.0323
Day 8		
Number of subjects with a response, n (%) [2]	24 (45.3)	33 (71.7)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.585
95% CI for the RR		(1.120, 2.243)
p-value for RR		0.0093

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 15		
Number of subjects with a response, n (%) [2]	23 (43.4)	35 (76.1)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.755
95% CI for the RR		(1.240, 2.482)
p-value for RR		0.0015
Day 21		
Number of subjects with a response, n (%) [2]	26 (49.1)	37 (80.4)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.641
95% CI for the RR		(1.204, 2.237)
p-value for RR		0.0017

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 45		
Number of subjects with a response, n (%) [2]	26 (49.1)	34 (73.9)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.508
95% CI for the RR		(1.092, 2.083)
p-value for RR		0.0127

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.1.2.1 .2 .2 .3 Abstammung

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 3		
Number of subjects with a response, n (%) [2]	7 (21.9)	11 (35.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.603
95% CI for the RR		(0.714, 3.598)
p-value for RR		0.2526
Day 8		
Number of subjects with a response, n (%) [2]	13 (40.6)	18 (58.1)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.412
95% CI for the RR		(0.852, 2.342)
p-value for RR		0.1806

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 15		
Number of subjects with a response, n (%) [2]	14 (43.8)	21 (67.7)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.530
95% CI for the RR		(0.974, 2.405)
p-value for RR		0.0652
Day 21		
Number of subjects with a response, n (%) [2]	19 (59.4)	18 (58.1)
Number of subjects with missing evaluation, n (%)	1 (3.1)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.966
95% CI for the RR		(0.640, 1.460)
p-value for RR		0.8711

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 45		
Number of subjects with a response, n (%) [2]	17 (53.1)	21 (67.7)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.260
95% CI for the RR		(0.837, 1.897)
p-value for RR		0.2680

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 3		
Number of subjects with a response, n (%) [2]	13 (32.5)	18 (40.9)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.257
95% CI for the RR		(0.707, 2.234)
p-value for RR		0.4358
Day 8		
Number of subjects with a response, n (%) [2]	19 (47.5)	30 (68.2)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.433
95% CI for the RR		(0.979, 2.099)
p-value for RR		0.0645

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	19 (47.5)	31 (70.5)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.481
95% CI for the RR		(1.015, 2.161)
p-value for RR		0.0416
Day 21		
Number of subjects with a response, n (%) [2]	21 (52.5)	35 (79.5)
Number of subjects with missing evaluation, n (%)	1 (2.5)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.513
95% CI for the RR		(1.085, 2.111)
p-value for RR		0.0148

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	21 (52.5)	33 (75.0)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.427
95% CI for the RR		(1.016, 2.004)
p-value for RR		0.0404

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.1.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 3		
Number of subjects with a response, n (%) [2]	4 (30.8)	5 (31.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.991
95% CI for the RR		(0.296, 3.315)
p-value for RR		0.9878
Day 8		
Number of subjects with a response, n (%) [2]	5 (38.5)	11 (68.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.744
95% CI for the RR		(0.731, 4.157)
p-value for RR		0.2099

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 15		
Number of subjects with a response, n (%) [2]	6 (46.2)	11 (68.8)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.453
95% CI for the RR		(0.646, 3.269)
p-value for RR		0.3666
Day 21		
Number of subjects with a response, n (%) [2]	5 (38.5)	12 (75.0)
Number of subjects with missing evaluation, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.902
95% CI for the RR		(0.779, 4.642)
p-value for RR		0.1579

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 45		
Number of subjects with a response, n (%) [2]	6 (46.2)	12 (75.0)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.585
95% CI for the RR		(0.703, 3.575)
p-value for RR		0.2670

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 3		
Number of subjects with a response, n (%) [2]	16 (25.8)	25 (41.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.630
95% CI for the RR		(0.973, 2.730)
p-value for RR		0.0634
Day 8		
Number of subjects with a response, n (%) [2]	28 (45.2)	38 (63.3)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.416
95% CI for the RR		(1.014, 1.975)
p-value for RR		0.0410

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 15		
Number of subjects with a response, n (%) [2]	29 (46.8)	42 (70.0)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.511
95% CI for the RR		(1.107, 2.062)
p-value for RR		0.0094
Day 21		
Number of subjects with a response, n (%) [2]	36 (58.1)	41 (68.3)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.188
95% CI for the RR		(0.904, 1.562)
p-value for RR		0.2174

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 45		
Number of subjects with a response, n (%) [2]	33 (53.2)	43 (71.7)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.359
95% CI for the RR		(1.025, 1.803)
p-value for RR		0.0332

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.1.2.1 .2 .2 .5 BMI

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 3		
Number of subjects with a response, n (%) [2]	8 (38.1)	5 (38.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.093
95% CI for the RR		(0.453, 2.636)
p-value for RR		0.8431
Day 8		
Number of subjects with a response, n (%) [2]	9 (42.9)	6 (46.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.166
95% CI for the RR		(0.538, 2.524)
p-value for RR		0.6970

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 15		
Number of subjects with a response, n (%) [2]	8 (38.1)	8 (61.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.749
95% CI for the RR		(0.902, 3.389)
p-value for RR		0.0978
Day 21		
Number of subjects with a response, n (%) [2]	10 (47.6)	9 (69.2)
Number of subjects with missing evaluation, n (%)	2 (9.5)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.574
95% CI for the RR		(0.891, 2.780)
p-value for RR		0.1181

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 45		
Number of subjects with a response, n (%) [2]	10 (47.6)	10 (76.9)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.749
95% CI for the RR		(1.007, 3.036)
p-value for RR		0.0470

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 3		
Number of subjects with a response, n (%) [2]	1 (5.0)	11 (52.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		10.401
95% CI for the RR		(1.469, 73.640)
p-value for RR		0.0190
Day 8		
Number of subjects with a response, n (%) [2]	5 (25.0)	17 (81.0)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		3.215
95% CI for the RR		(1.479, 6.989)
p-value for RR		0.0032

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	7 (35.0)	18 (85.7)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.431
95% CI for the RR		(1.318, 4.483)
p-value for RR		0.0044
Day 21		
Number of subjects with a response, n (%) [2]	9 (45.0)	16 (76.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.681
95% CI for the RR		(0.983, 2.874)
p-value for RR		0.0577

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 45		
Number of subjects with a response, n (%) [2]	10 (50.0)	19 (90.5)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.796
95% CI for the RR		(1.136, 2.841)
p-value for RR		0.0123

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 3		
Number of subjects with a response, n (%) [2]	11 (32.4)	14 (33.3)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.028
95% CI for the RR		(0.536, 1.972)
p-value for RR		0.9341
Day 8		
Number of subjects with a response, n (%) [2]	19 (55.9)	26 (61.9)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.105
95% CI for the RR		(0.754, 1.619)
p-value for RR		0.6077

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 15		
Number of subjects with a response, n (%) [2]	20 (58.8)	27 (64.3)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.090
95% CI for the RR		(0.760, 1.565)
p-value for RR		0.6392
Day 21		
Number of subjects with a response, n (%) [2]	22 (64.7)	28 (66.7)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.028
95% CI for the RR		(0.740, 1.428)
p-value for RR		0.8698

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 45		
Number of subjects with a response, n (%) [2]	19 (55.9)	26 (61.9)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.105
95% CI for the RR		(0.754, 1.619)
p-value for RR		0.6080

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.1.2.1 .2 .2 .6 Beginn der PPD

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 3		
Number of subjects with a response, n (%) [2]	9 (28.1)	15 (46.9)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.667
95% CI for the RR		(0.857, 3.242)
p-value for RR		0.1320
Day 8		
Number of subjects with a response, n (%) [2]	15 (46.9)	22 (68.8)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.467
95% CI for the RR		(0.952, 2.260)
p-value for RR		0.0821

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 15		
Number of subjects with a response, n (%) [2]	14 (43.8)	23 (71.9)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.643
95% CI for the RR		(1.052, 2.567)
p-value for RR		0.0290
Day 21		
Number of subjects with a response, n (%) [2]	18 (56.3)	22 (68.8)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.223
95% CI for the RR		(0.833, 1.795)
p-value for RR		0.3050

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 45		
Number of subjects with a response, n (%) [2]	18 (56.3)	25 (78.1)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.389
95% CI for the RR		(0.976, 1.977)
p-value for RR		0.0676

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 3		
Number of subjects with a response, n (%) [2]	11 (25.6)	15 (34.1)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.345
95% CI for the RR		(0.700, 2.584)
p-value for RR		0.3731
Day 8		
Number of subjects with a response, n (%) [2]	18 (41.9)	27 (61.4)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.480
95% CI for the RR		(0.968, 2.263)
p-value for RR		0.0706

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	21 (48.8)	30 (68.2)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.409
95% CI for the RR		(0.975, 2.038)
p-value for RR		0.0682
Day 21		
Number of subjects with a response, n (%) [2]	23 (53.5)	31 (70.5)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.330
95% CI for the RR		(0.944, 1.873)
p-value for RR		0.1027

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	21 (48.8)	30 (68.2)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.409
95% CI for the RR		(0.972, 2.043)
p-value for RR		0.0702

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.1.2.1 .2 .2 .7 PPD in der Familie

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 3		
Number of subjects with a response, n (%) [2]	2 (20.0)	3 (30.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.454
95% CI for the RR		(0.320, 6.601)
p-value for RR		0.6279
Day 8		
Number of subjects with a response, n (%) [2]	3 (30.0)	8 (80.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.585
95% CI for the RR		(0.992, 6.731)
p-value for RR		0.0519

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	4 (40.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.696
95% CI for the RR		(0.737, 3.906)
p-value for RR		0.2145
Day 21		
Number of subjects with a response, n (%) [2]	4 (40.0)	9 (90.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.181
95% CI for the RR		(1.050, 4.529)
p-value for RR		0.0365

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	6 (60.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.969
95% CI for the RR		(0.477, 1.968)
p-value for RR		0.9310

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 3		
Number of subjects with a response, n (%) [2]	18 (27.7)	27 (40.9)
Number of subjects with missing evaluation, n (%)	1 (1.5)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.482
95% CI for the RR		(0.913, 2.407)
p-value for RR		0.1117
Day 8		
Number of subjects with a response, n (%) [2]	30 (46.2)	41 (62.1)
Number of subjects with missing evaluation, n (%)	1 (1.5)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.350
95% CI for the RR		(0.979, 1.862)
p-value for RR		0.0669

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	31 (47.7)	46 (69.7)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.466
95% CI for the RR		(1.087, 1.977)
p-value for RR		0.0121
Day 21		
Number of subjects with a response, n (%) [2]	37 (56.9)	44 (66.7)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.175
95% CI for the RR		(0.896, 1.541)
p-value for RR		0.2439

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	33 (50.8)	49 (74.2)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.467
95% CI for the RR		(1.110, 1.939)
p-value for RR		0.0071

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.1.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 3		
Number of subjects with a response, n (%) [2]	18 (30.5)	25 (37.9)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.256
95% CI for the RR		(0.768, 2.054)
p-value for RR		0.3647
Day 8		
Number of subjects with a response, n (%) [2]	27 (45.8)	43 (65.2)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.440
95% CI for the RR		(1.039, 1.995)
p-value for RR		0.0285

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	30 (50.8)	48 (72.7)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.446
95% CI for the RR		(1.082, 1.934)
p-value for RR		0.0127
Day 21		
Number of subjects with a response, n (%) [2]	34 (57.6)	46 (69.7)
Number of subjects with missing evaluation, n (%)	1 (1.7)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.223
95% CI for the RR		(0.934, 1.601)
p-value for RR		0.1431

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	33 (55.9)	49 (74.2)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.342
95% CI for the RR		(1.028, 1.752)
p-value for RR		0.0303

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 3		
Number of subjects with a response, n (%) [2]	2 (12.5)	5 (50.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.588
95% CI for the RR		(0.814, 15.821)
p-value for RR		0.0915
Day 8		
Number of subjects with a response, n (%) [2]	6 (37.5)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.435
95% CI for the RR		(0.599, 3.436)
p-value for RR		0.4174

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	5 (31.3)	5 (50.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.435
95% CI for the RR		(0.524, 3.931)
p-value for RR		0.4823
Day 21		
Number of subjects with a response, n (%) [2]	7 (43.8)	7 (70.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.435
95% CI for the RR		(0.687, 2.996)
p-value for RR		0.3361

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	6 (37.5)	6 (60.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.435
95% CI for the RR		(0.609, 3.380)
p-value for RR		0.4085

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

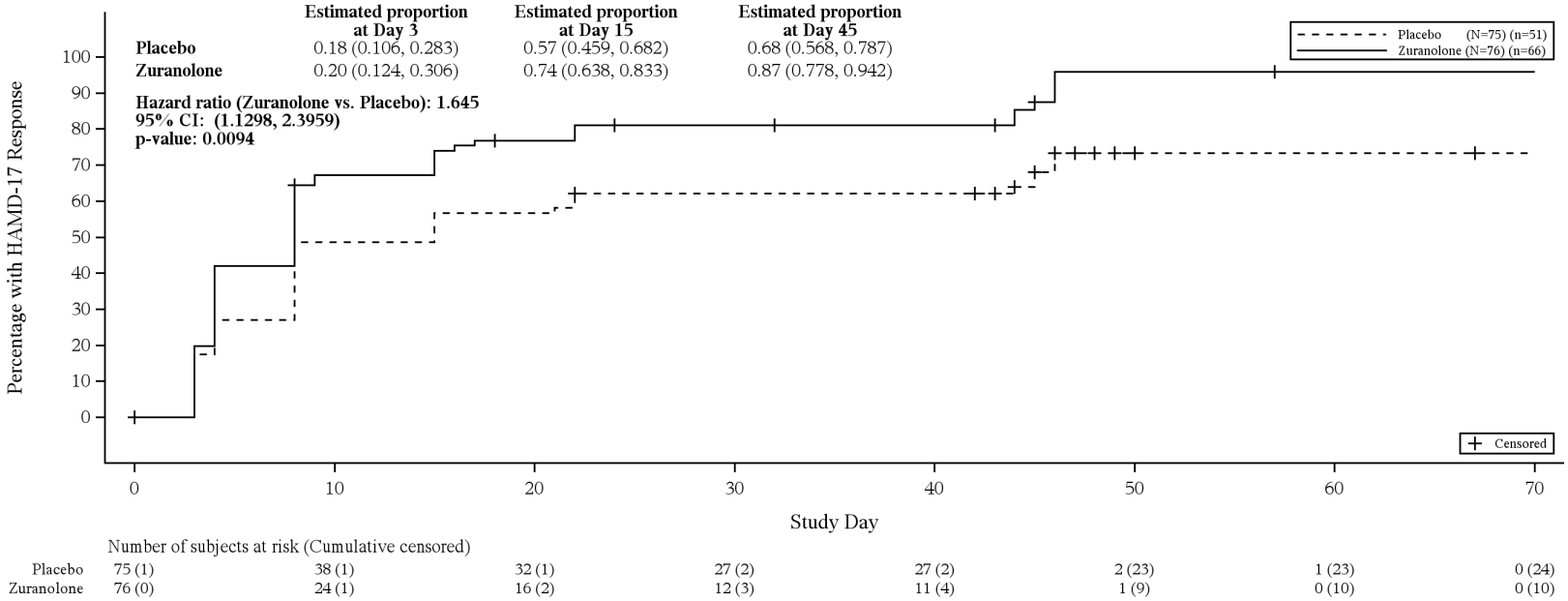
Source: biib125/v_a/germany_amnog/t-hamd-resp50-201-by.sas:t-hamd-resp50-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.1.2.2 TTE-Analysen

4.1.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-ovr.sas:f-hamd-resp50-tte-201-ovr-itta.rtf **Run Date:** 16DEC2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	51 (68.0)	66 (86.8)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0 , 22.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	16.0 (8.0 , 44.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.645
95% CI for the HR		(1.1298 , 2.3959)
p-value for the HR		0.0094

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-ovr.sas:t-hamd-resp50-tte-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.1.2.2 .2 Subgruppen

4.1.2.2 .2 .1 Interaktionstest

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	51 (68.0)	66 (86.8)	
Age Group (years)			
18 - 24, n / N (%)	18/25 (72.0)	15/17 (88.2)	0.7571
25 - 45, n / N (%)	33/50 (66.0)	51/59 (86.4)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	17/22 (77.3)	24/30 (80.0)	0.1275
>=28, n / N (%)	34/53 (64.2)	42/46 (91.3)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	21/32 (65.6)	25/31 (80.6)	0.6857
White, n / N (%)	28/40 (70.0)	40/44 (90.9)	
Antidepressant Use at Baseline			
Yes, n / N (%)	9/13 (69.2)	15/16 (93.8)	0.8459
No, n / N (%)	42/62 (67.7)	51/60 (85.0)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-int.sas:t-hamd-resp50-tte-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	13/21 (61.9)	12/13 (92.3)	0.2610(a)
25-29.9, n / N (%)	12/20 (60.0)	19/21 (90.5)	0.4033(b)
>=30, n / N (%)	26/34 (76.5)	35/42 (83.3)	0.0261(c)
Onset of PPD			
3rd Trimester, n / N (%)	24/32 (75.0)	28/32 (87.5)	0.7361
Postpartum, n / N (%)	27/43 (62.8)	38/44 (86.4)	
Family History of PPD			
Yes, n / N (%)	7/10 (70.0)	10/10 (100.0)	0.5390
No/Unknown, n / N (%)	44/65 (67.7)	56/66 (84.8)	
History of PPD			
1st Episode, n / N (%)	43/59 (72.9)	58/66 (87.9)	0.5551
Recurrent Episode, n / N (%)	8/16 (50.0)	8/10 (80.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	7/8 (87.5)	9/10 (90.0)	NA
>=20, n / N (%)	44/67 (65.7)	57/66 (86.4)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-int.sas:t-hamd-resp50-tte-201-int-itta.rtf **Run Date:** 29JUL2025

4.1.2.2 .2 .2 Subgruppenanalysen

4.1.2.2 .2 .2 .1 Alter

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	18 (72.0)	15 (88.2)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (4.0 , 46.0)	4.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	46.0 (15.0, NE)	15.0 (4.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.968
95% CI for the HR		(0.9496 , 4.0787)
p-value for the HR		0.0686

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	33 (66.0)	51 (86.4)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0 , 22.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	16.0 (9.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.563
95% CI for the HR		(0.9953 , 2.4547)
p-value for the HR		0.0525

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.1.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	17 (77.3)	24 (80.0)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	11.5 (4.0 , 22.0)	8.0 (4.0 , 22.0)
75th percentile - Q3 (95% CI)	46.0 (15.0, NE)	44.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.168
95% CI for the HR		(0.6224 , 2.1922)
p-value for the HR		0.6285

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	34 (64.2)	42 (91.3)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	6.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0 , 45.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	15.0 (8.0 , 17.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.999
95% CI for the HR		(1.2526 , 3.1911)
p-value for the HR		0.0037

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.1.2.2 .2 .2 .3 Abstammung

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	21 (65.6)	25 (80.6)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0 , 46.0)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (21.0, NE)	45.0 (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.462
95% CI for the HR		(0.7935 , 2.6946)
p-value for the HR		0.2231

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	28 (70.0)	40 (90.9)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 45.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	15.0 (8.0 , 44.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.730
95% CI for the HR		(1.0499 , 2.8508)
p-value for the HR		0.0315

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.1.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	9 (69.2)	15 (93.8)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 22.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	22.0 (3.0, NE)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (8.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.923
95% CI for the HR		(0.8131 , 4.5489)
p-value for the HR		0.1365

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	42 (67.7)	51 (85.0)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0 , 22.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	16.5 (8.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.592
95% CI for the HR		(1.0444 , 2.4266)
p-value for the HR		0.0306

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.1.2.2 .2 .2 .5 BMI

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	13 (61.9)	12 (92.3)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (4.0, NE)	15.0 (4.0 , 22.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	22.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.012
95% CI for the HR		(0.8504 , 4.7600)
p-value for the HR		0.1116

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	12 (60.0)	19 (90.5)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	11.5 (3.0 , 15.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	33.5 (8.0, NE)	4.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	8.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.676
95% CI for the HR		(1.6338 , 8.2696)
p-value for the HR		0.0017

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	26 (76.5)	35 (83.3)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (4.0 , 15.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	46.0 (8.0, NE)	22.0 (8.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.148
95% CI for the HR		(0.6879 , 1.9157)
p-value for the HR		0.5973

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.1.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	24 (75.0)	28 (87.5)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 44.0)	8.0 (3.0 , 9.0)
75th percentile - Q3 (95% CI)	46.0 (15.0, NE)	15.0 (8.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.596
95% CI for the HR		(0.8950 , 2.8471)
p-value for the HR		0.1132

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	27 (62.8)	38 (86.4)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0, NE)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	17.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.705
95% CI for the HR		(1.0296 , 2.8238)
p-value for the HR		0.0381

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.1.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	7 (70.0)	10 (100.0)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 45.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	33.5 (3.0, NE)	8.0 (3.0 , 8.0)
75th percentile - Q3 (95% CI)	46.0 (22.0, NE)	8.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.666
95% CI for the HR		(0.7750 , 9.1689)
p-value for the HR		0.1198

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	44 (67.7)	56 (84.8)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	11.5 (8.0 , 22.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	17.0 (9.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.520
95% CI for the HR		(1.0096 , 2.2882)
p-value for the HR		0.0449

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.1.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	43 (72.9)	58 (87.9)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 22.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	46.0 (22.0, NE)	15.0 (8.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.578
95% CI for the HR		(1.0529 , 2.3660)
p-value for the HR		0.0271

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	8 (50.0)	8 (80.0)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 15.0)	3.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0, NE)	6.0 (3.0 , 44.0)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	44.0 (4.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.458
95% CI for the HR		(0.4707 , 4.5166)
p-value for the HR		0.5133

NOTE 1: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

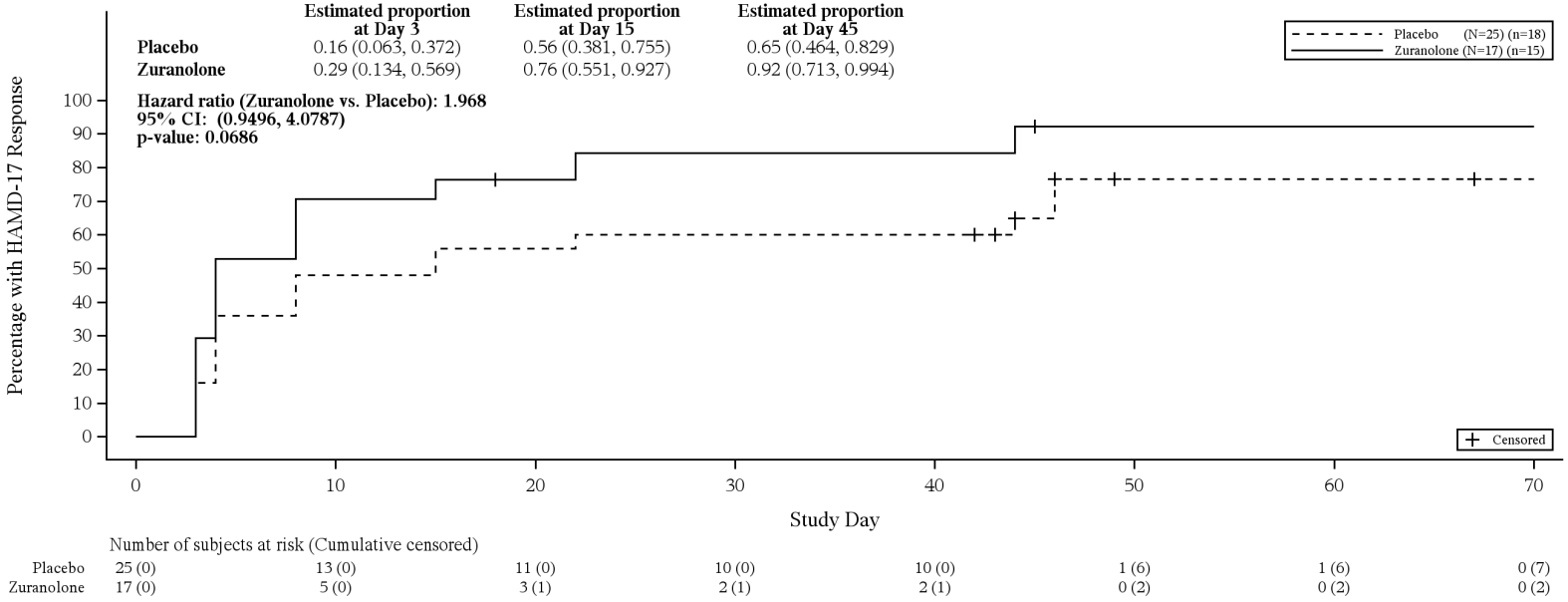
Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-201-by.sas:t-hamd-resp50-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.1.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

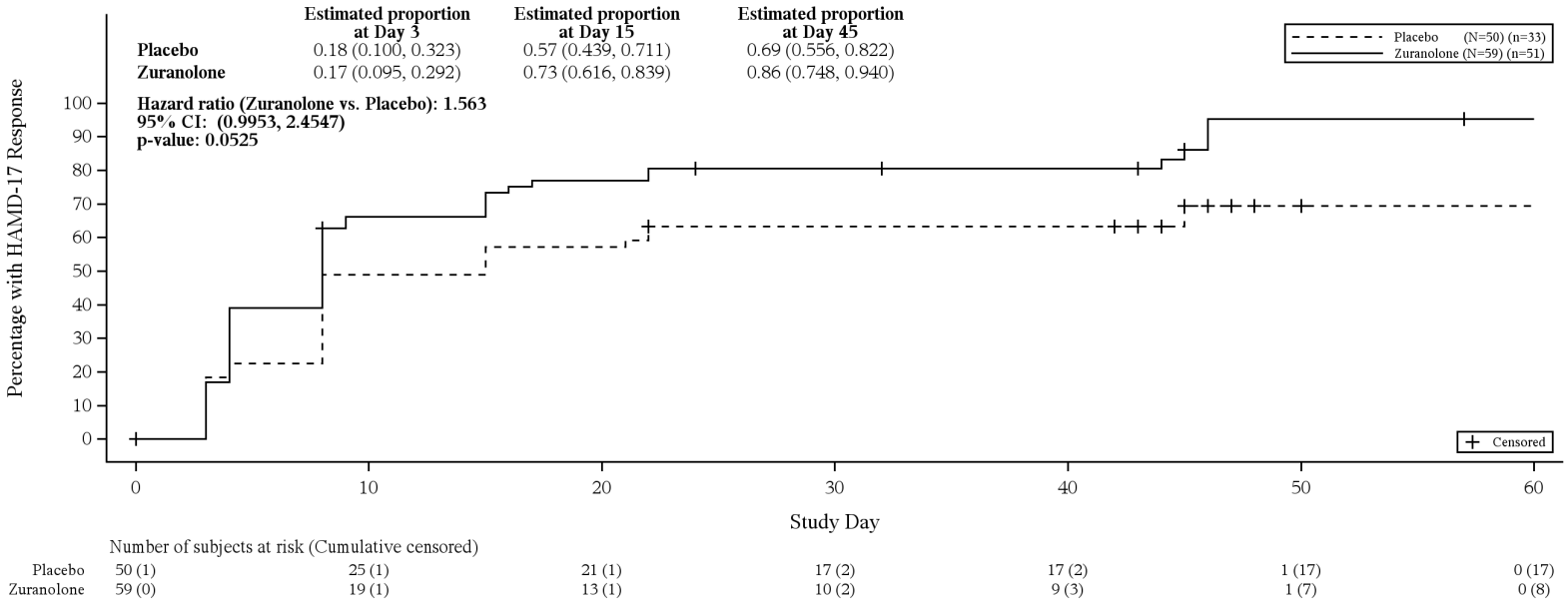
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Number of subjects at risk (Cumulative censored)

Placebo	50 (1)	25 (1)	21 (1)	17 (2)	17 (2)	1 (17)	0 (17)
Zuranolone	59 (0)	19 (1)	13 (1)	10 (2)	9 (3)	1 (7)	0 (8)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

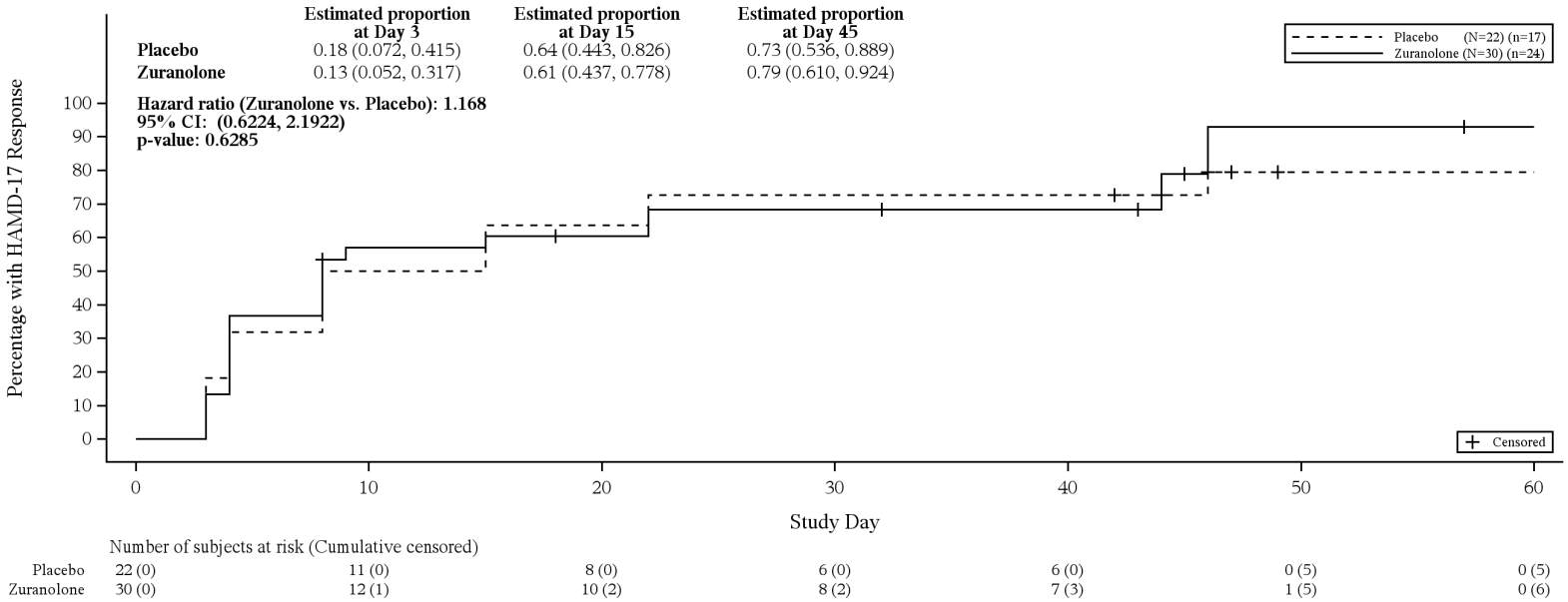
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

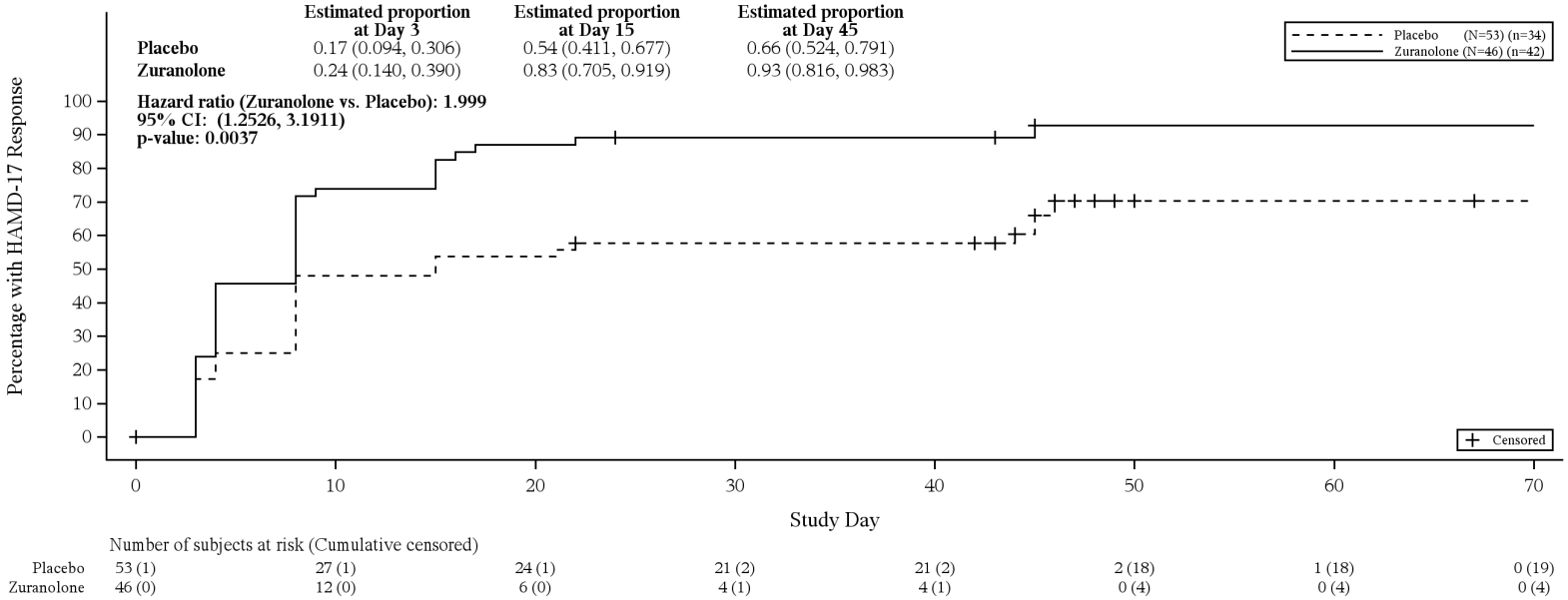
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

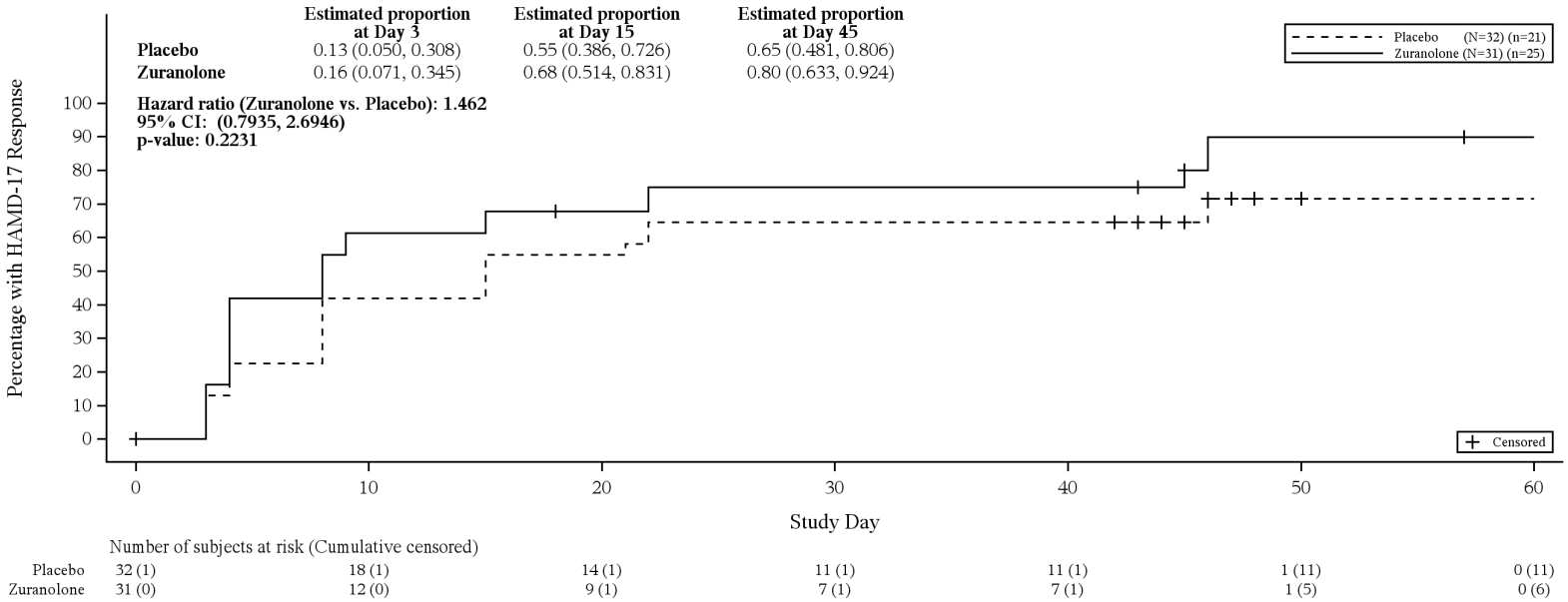
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

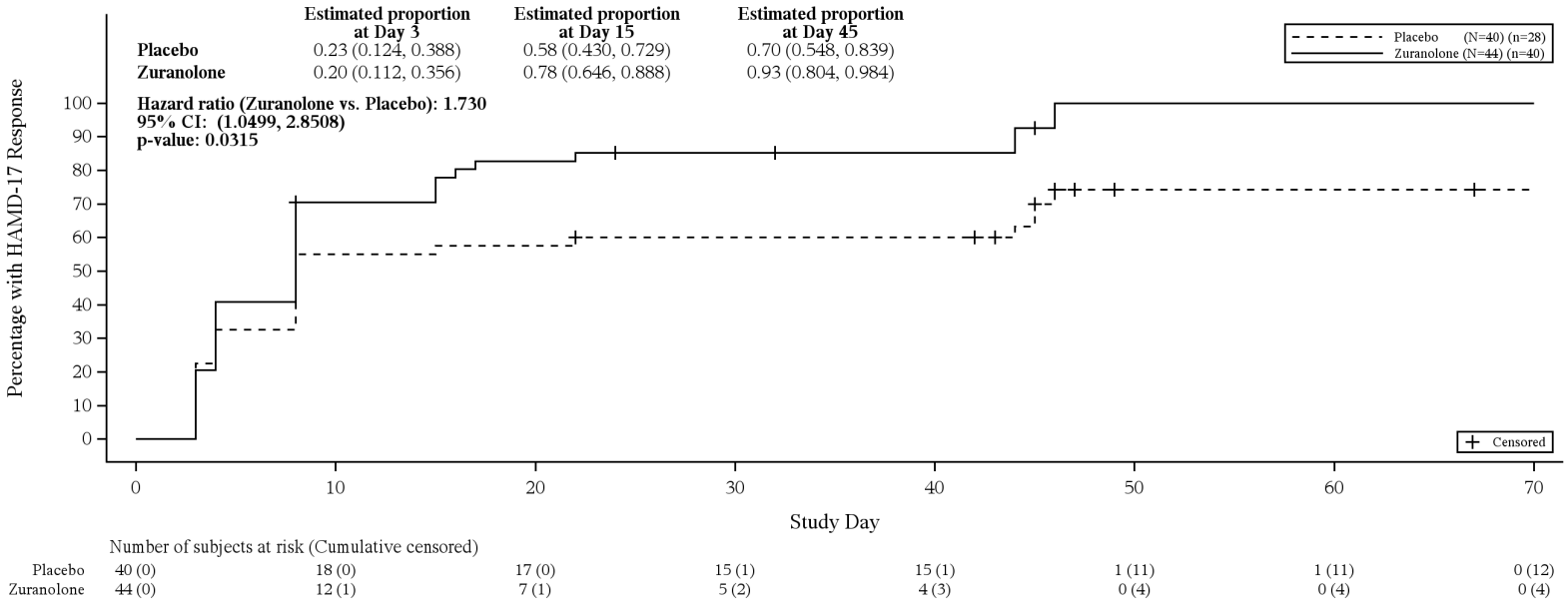
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Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

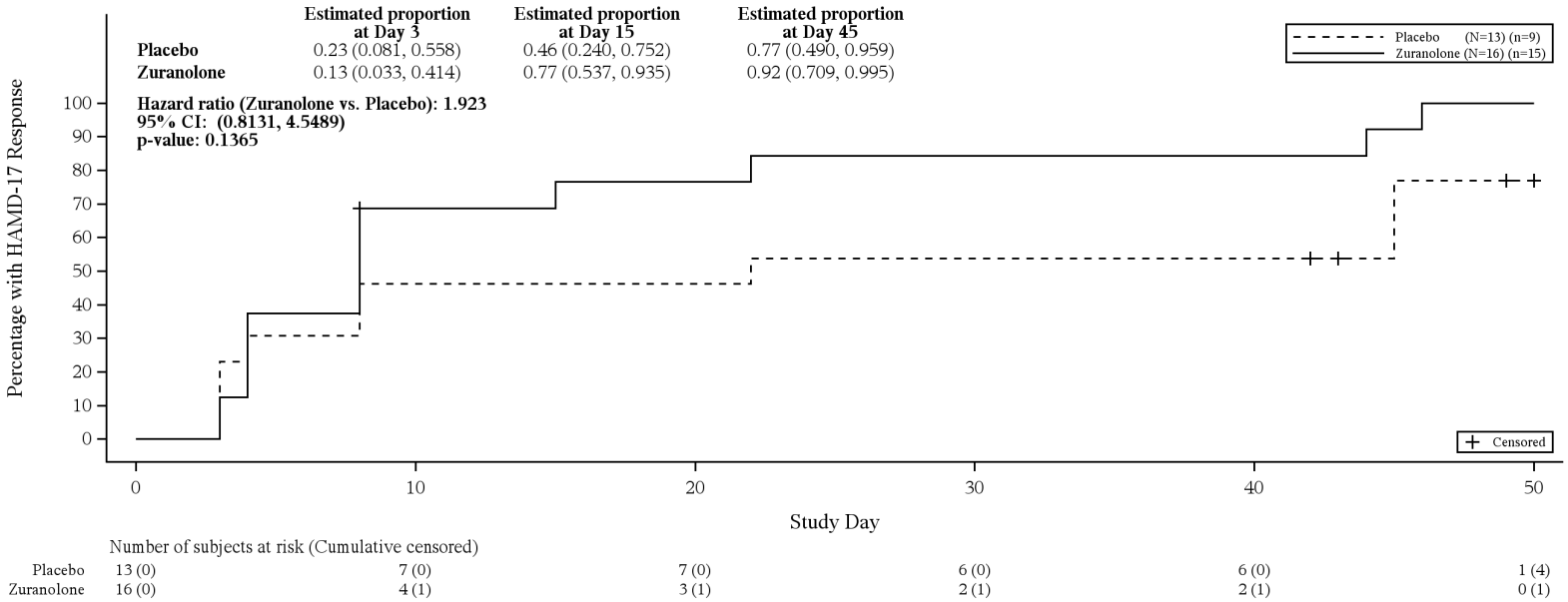
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

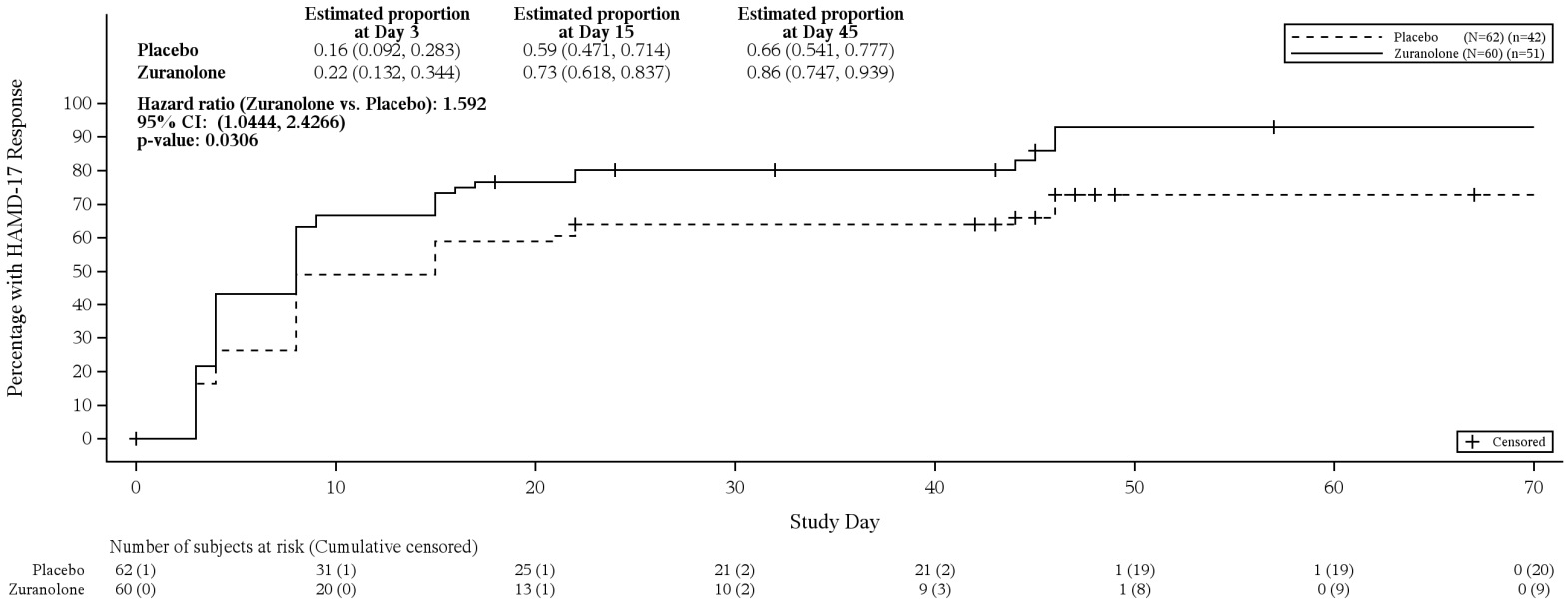
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

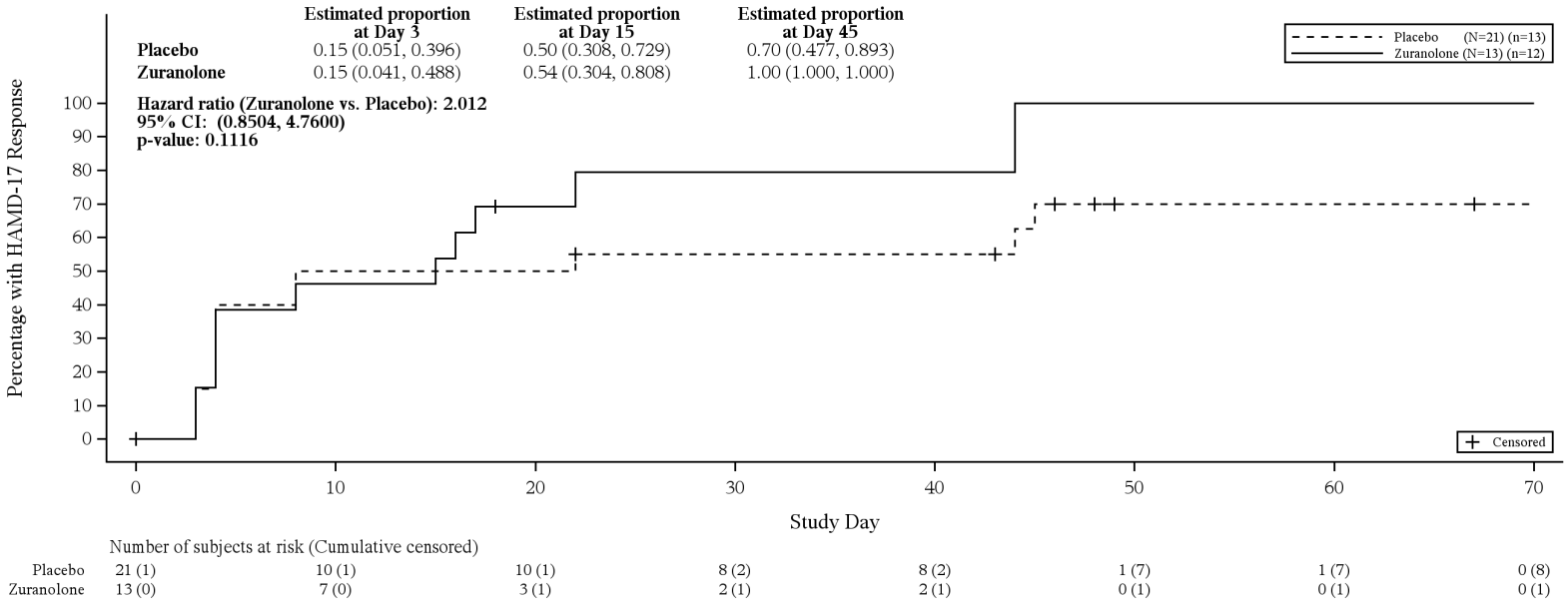
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

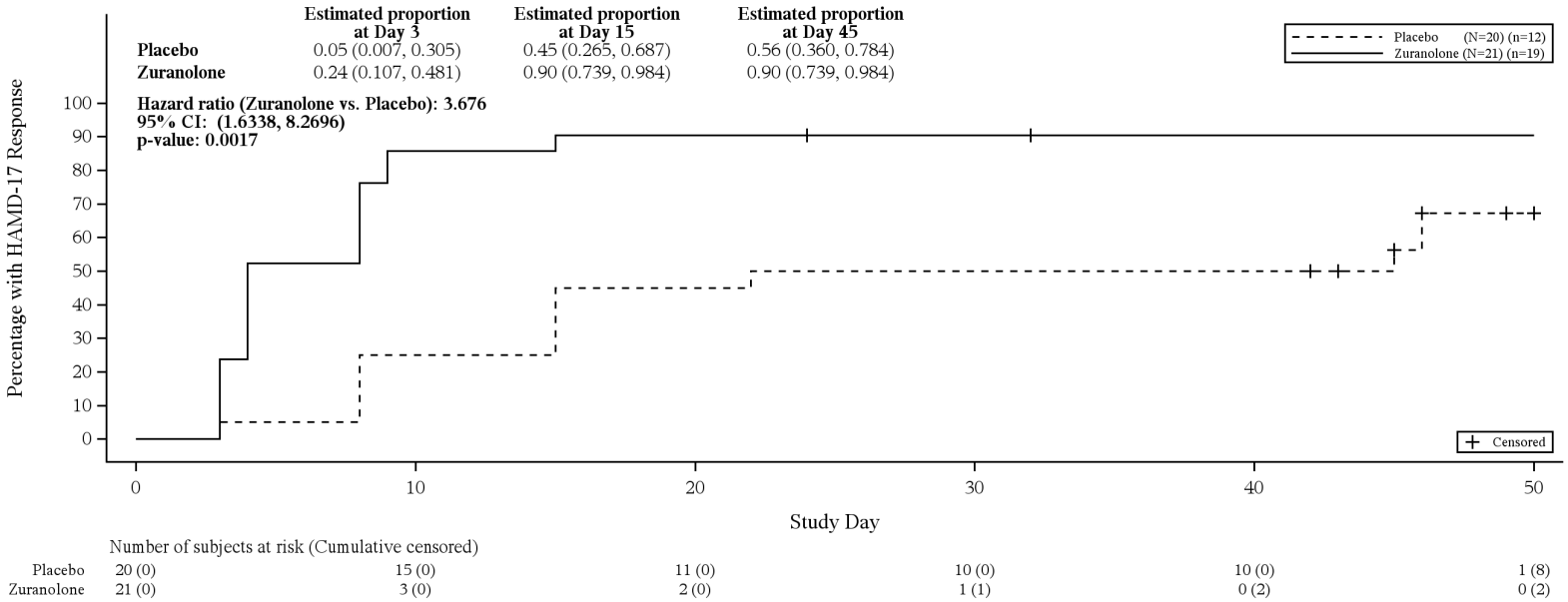
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

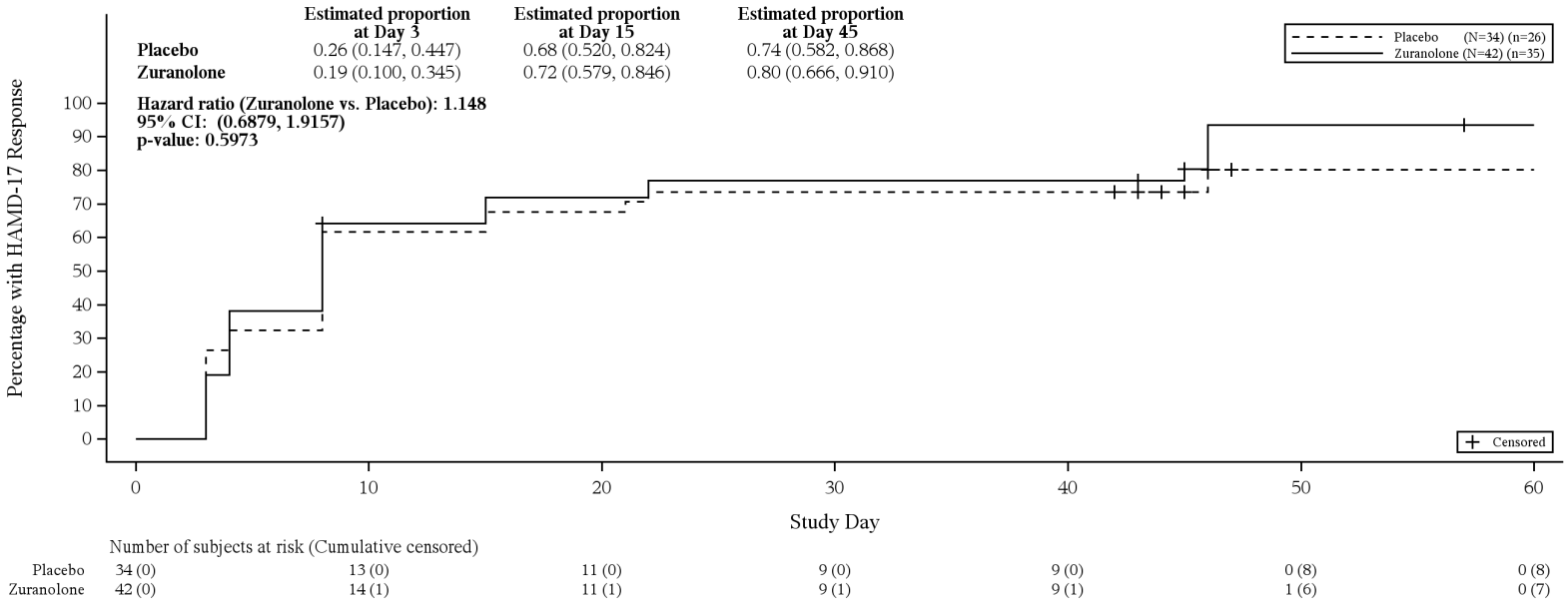
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

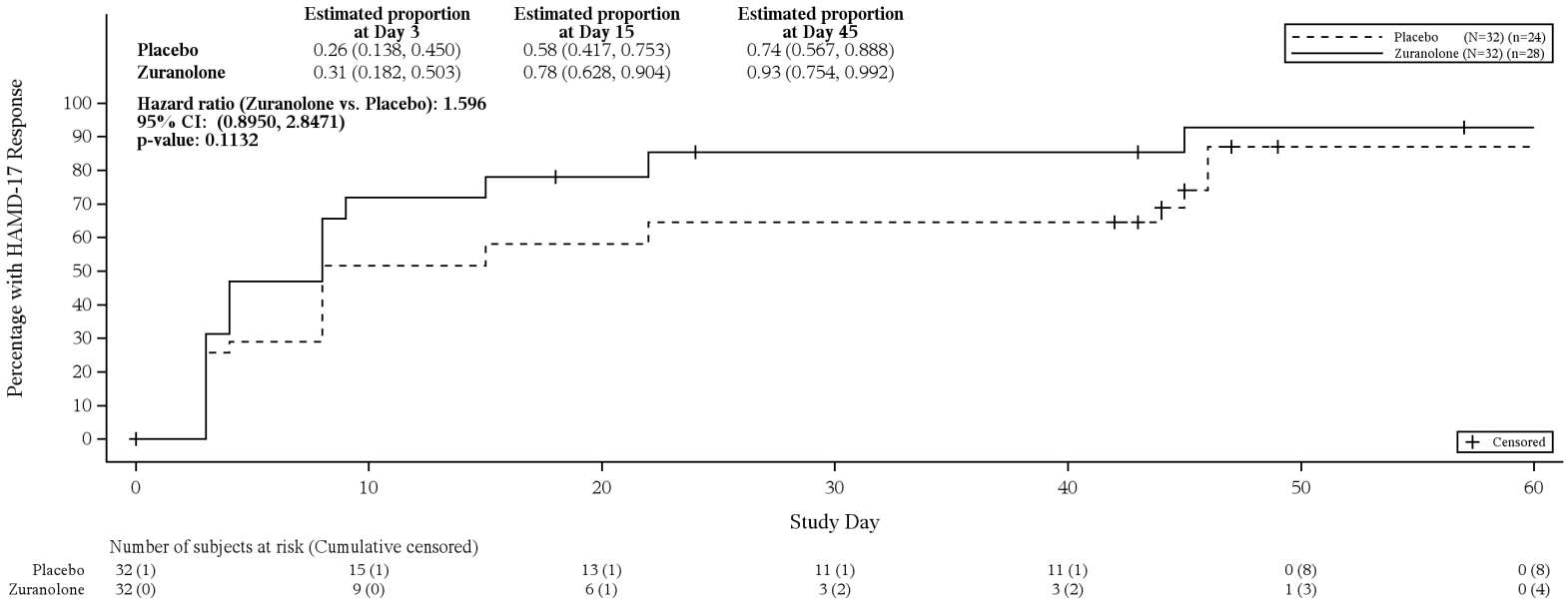
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

Page: 12 of 17

Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

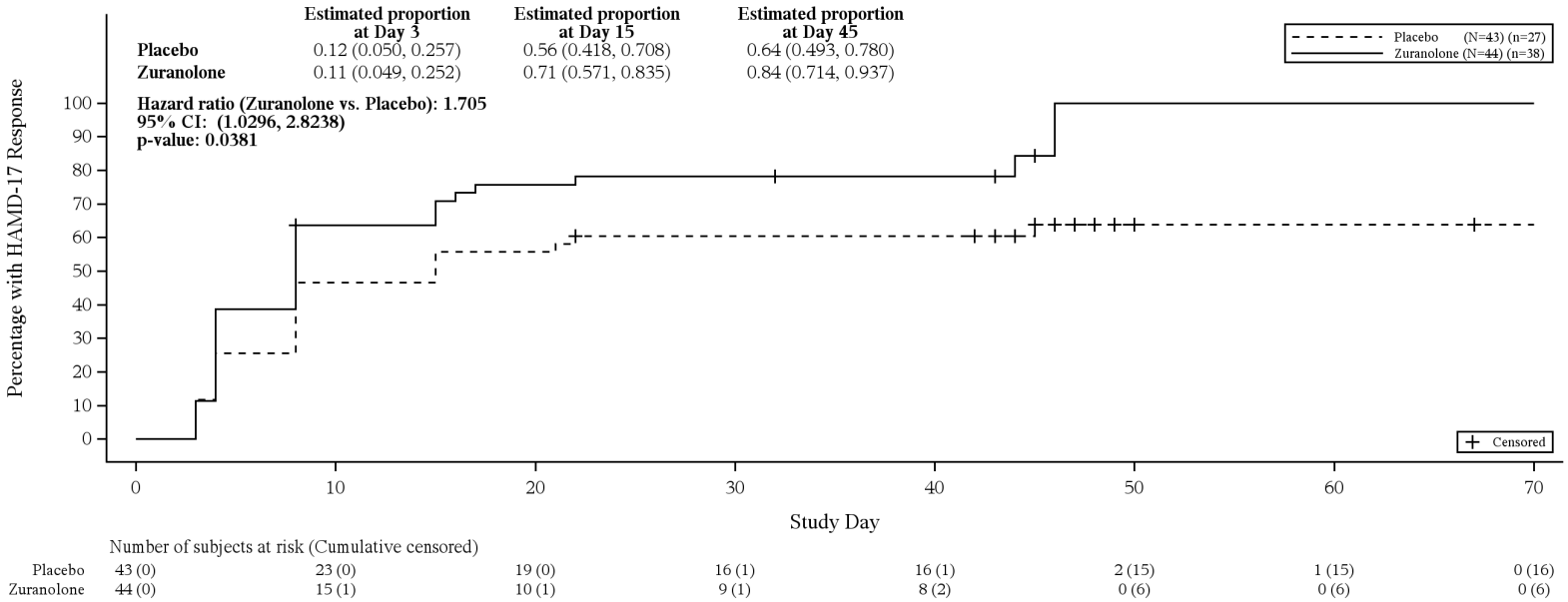
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Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

Page: 13 of 17

Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

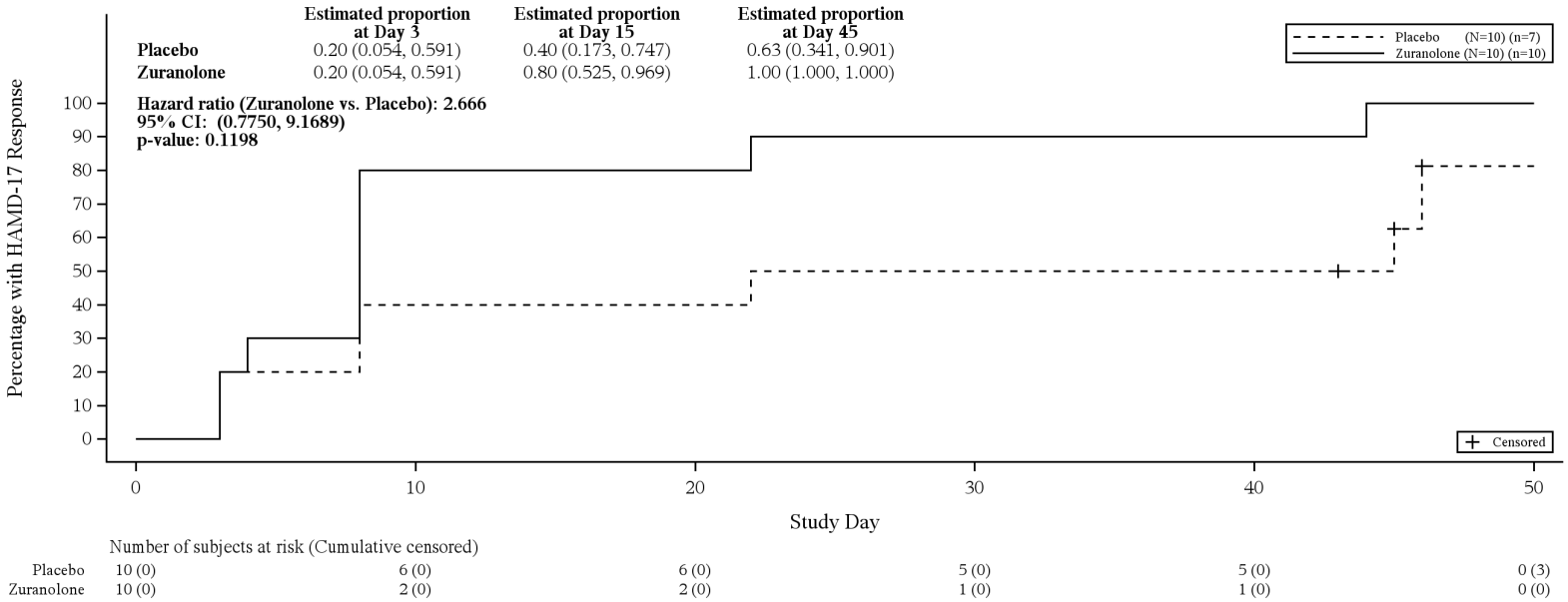
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

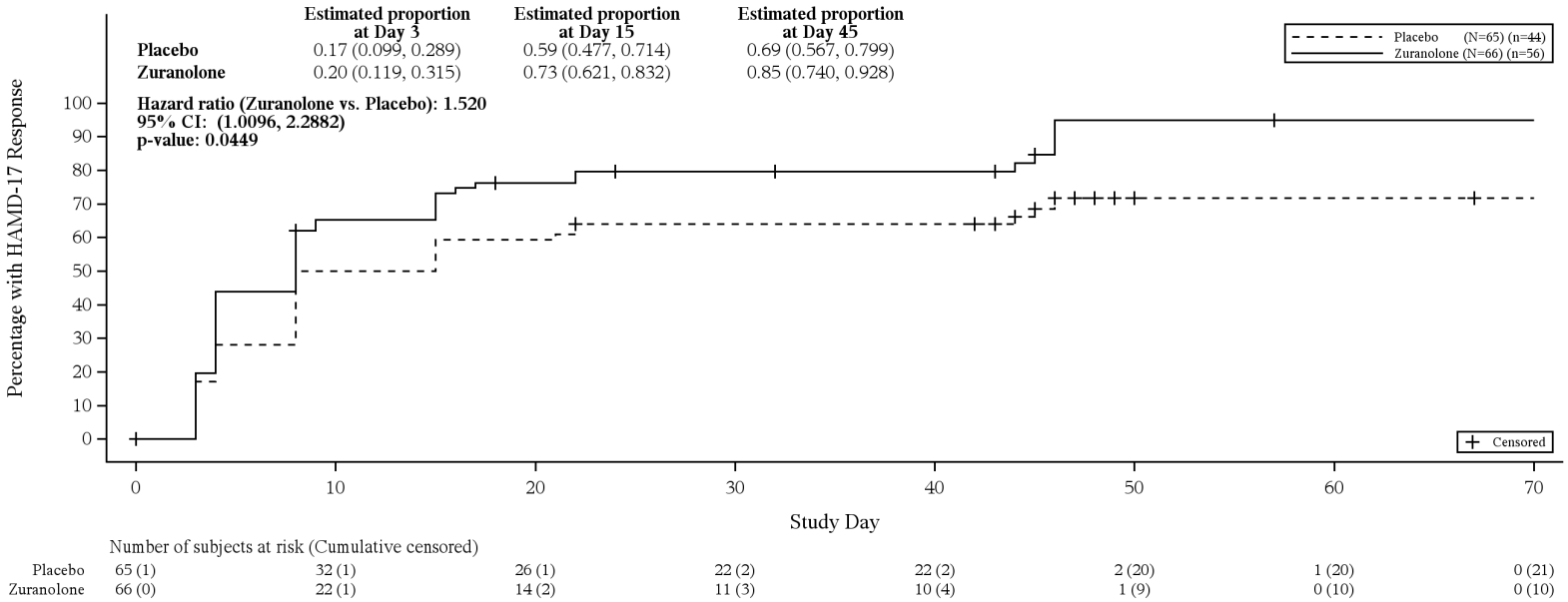
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

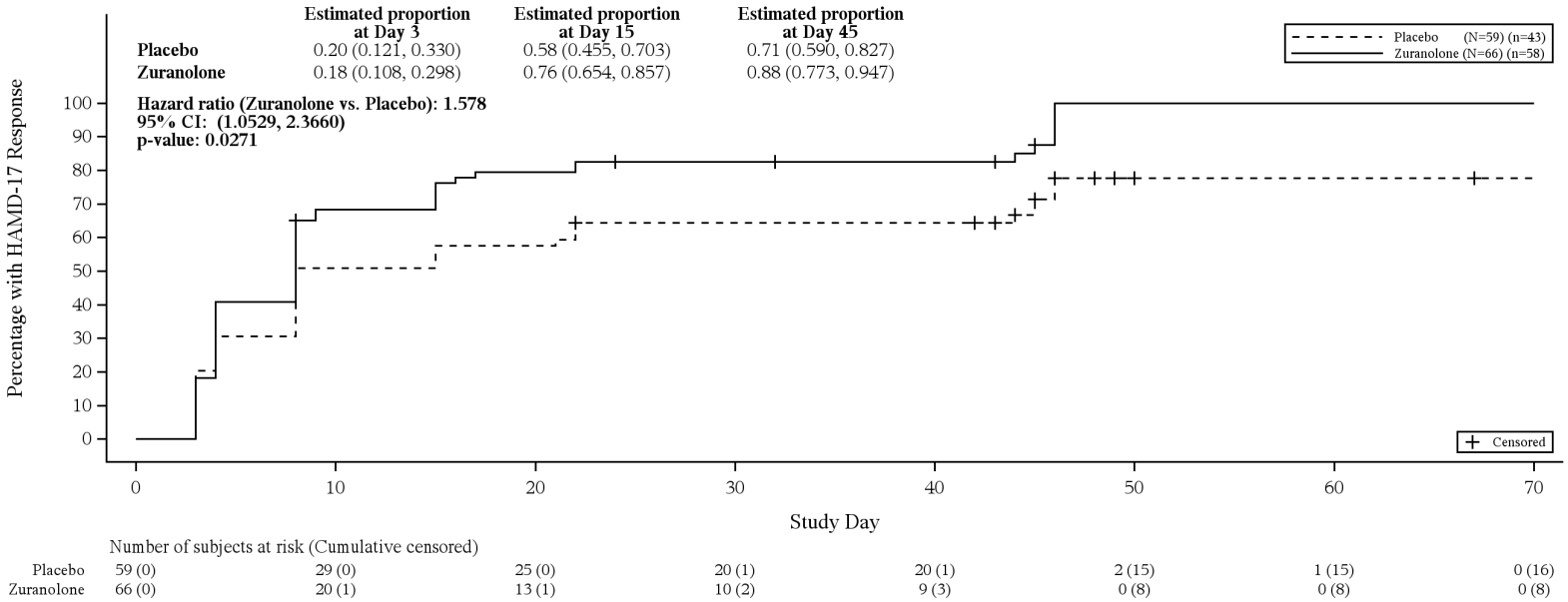
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

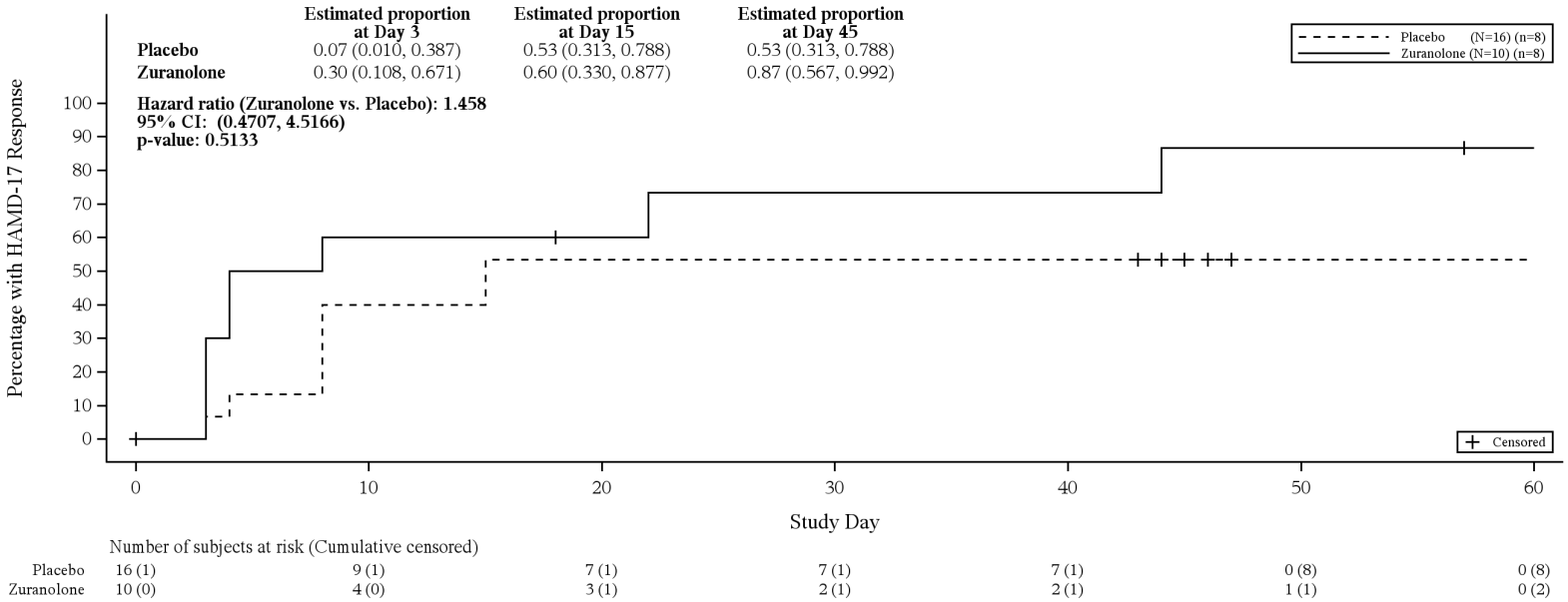
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-201-by.sas:f-hamd-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

4.1.3 Remission

4.1.3.1 Responder-Analysen

4.1.3.1 .1 ITT-Population

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with a remission, n (%) [2]	4 (5.3)	14 (18.4)
Number of subjects with missing evaluation, n (%)	1 (1.3)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		3.420
95% CI for the RR		(1.187, 9.859)
p-value for RR		0.0228
OR - Odds Ratio (Zuranolone vs. Placebo)		3.889
95% CI for the OR		(1.236, 12.235)
p-value for OR		0.0202
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-ovr.sas:t-hamd-remi-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with a remission, n (%) [2]	14 (18.7)	24 (31.6)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.655
95% CI for the RR		(0.927, 2.954)
p-value for RR		0.0882
OR - Odds Ratio (Zuranolone vs. Placebo)		1.940
95% CI for the OR		(0.904, 4.164)
p-value for OR		0.0890
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-ovr.sas:t-hamd-remi-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with a remission, n (%) [2]	17 (22.7)	33 (43.4)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.886
95% CI for the RR		(1.157, 3.076)
p-value for RR		0.0110
OR - Odds Ratio (Zuranolone vs. Placebo)		2.523
95% CI for the OR		(1.241, 5.130)
p-value for OR		0.0106
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-ovr.sas:t-hamd-remi-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with a remission, n (%) [2]	21 (28.0)	31 (40.8)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.447
95% CI for the RR		(0.917, 2.285)
p-value for RR		0.1126
OR - Odds Ratio (Zuranolone vs. Placebo)		1.702
95% CI for the OR		(0.850, 3.408)
p-value for OR		0.1336
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-ovr.sas:t-hamd-remi-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a remission, n (%) [2]	21 (28.0)	39 (51.3)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.807
95% CI for the RR		(1.182, 2.764)
p-value for RR		0.0063
OR - Odds Ratio (Zuranolone vs. Placebo)		2.620
95% CI for the OR		(1.323, 5.189)
p-value for OR		0.0057
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-ovr.sas:t-hamd-remi-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.1.3.1 .2 Subgruppen

4.1.3.1 .2 .1 Interaktionstest

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	17 (22.7)	33 (43.4)	
Number of subjects with response at Day 45, n (%)	21 (28.0)	39 (51.3)	
Age Group (years)			0.4474
Day 15			
18 - 24, n / N (%)	8/25 (32.0)	7/17 (41.2)	
25 - 45, n / N (%)	9/50 (18.0)	26/59 (44.1)	
Day 45			
18 - 24, n / N (%)	8/25 (32.0)	8/17 (47.1)	
25 - 45, n / N (%)	13/50 (26.0)	31/59 (52.5)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-int.sas:t-hamd-remi-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.3907
Day 15			
<28, n / N (%)	6/22 (27.3)	12/30 (40.0)	
>=28, n / N (%)	11/53 (20.8)	21/46 (45.7)	
Day 45			
<28, n / N (%)	7/22 (31.8)	15/30 (50.0)	
>=28, n / N (%)	14/53 (26.4)	24/46 (52.2)	
Race Group (Black or African American, White)			0.7773
Day 15			
Black or African American, n / N (%)	6/32 (18.8)	15/31 (48.4)	
White, n / N (%)	11/40 (27.5)	17/44 (38.6)	
Day 45			
Black or African American, n / N (%)	8/32 (25.0)	15/31 (48.4)	
White, n / N (%)	12/40 (30.0)	23/44 (52.3)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-int.sas:t-hamd-remi-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.7493
Day 15			
Yes, n / N (%)	5/13 (38.5)	9/16 (56.3)	
No, n / N (%)	12/62 (19.4)	24/60 (40.0)	
Day 45			
Yes, n / N (%)	4/13 (30.8)	10/16 (62.5)	
No, n / N (%)	17/62 (27.4)	29/60 (48.3)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-int.sas:t-hamd-remi-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.6530(a) 0.4748(b) 0.1571(c)
Day 15			
<=24.9, n / N (%)	6/21 (28.6)	5/13 (38.5)	
25-29.9, n / N (%)	1/20 (5.0)	10/21 (47.6)	
>=30, n / N (%)	10/34 (29.4)	18/42 (42.9)	
Day 45			
<=24.9, n / N (%)	5/21 (23.8)	8/13 (61.5)	
25-29.9, n / N (%)	7/20 (35.0)	14/21 (66.7)	
>=30, n / N (%)	9/34 (26.5)	17/42 (40.5)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-int.sas:t-hamd-remi-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.2939
Day 15			
3rd Trimester, n / N (%)	6/32 (18.8)	16/32 (50.0)	
Postpartum, n / N (%)	11/43 (25.6)	17/44 (38.6)	
Day 45			
3rd Trimester, n / N (%)	9/32 (28.1)	20/32 (62.5)	
Postpartum, n / N (%)	12/43 (27.9)	19/44 (43.2)	
Family History of PPD			0.6004
Day 15			
Yes, n / N (%)	2/10 (20.0)	4/10 (40.0)	
No/Unknown, n / N (%)	15/65 (23.1)	29/66 (43.9)	
Day 45			
Yes, n / N (%)	1/10 (10.0)	4/10 (40.0)	
No/Unknown, n / N (%)	20/65 (30.8)	35/66 (53.0)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-int.sas:t-hamd-remi-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.5492
Day 15			
1st Episode, n / N (%)	15/59 (25.4)	29/66 (43.9)	
Recurrent Episode, n / N (%)	2/16 (12.5)	4/10 (40.0)	
Day 45			
1st Episode, n / N (%)	17/59 (28.8)	34/66 (51.5)	
Recurrent Episode, n / N (%)	4/16 (25.0)	5/10 (50.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	2/8 (25.0)	5/10 (50.0)	
>=20, n / N (%)	15/67 (22.4)	28/66 (42.4)	
Day 45			
<20, n / N (%)	3/8 (37.5)	4/10 (40.0)	
>=20, n / N (%)	18/67 (26.9)	35/66 (53.0)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-int.sas:t-hamd-remi-201-int-itta.rtf **Run Date:** 29JUL2025

4.1.3.1 .2 .2 Subgruppenanalysen

4.1.3.1 .2 .2 .1 Alter

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit **Statistics**	**Placebo** **(N=26)**	**Zuranolone** **(N =18)**
Number of evaluable subjects [1]	25	17
Day 3		
Number of subjects with a remission, n (%) [2]	0	4 (23.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		13.00
95% CI for the RR		(0.745, 226.834)
p-value for RR		0.0787
Day 8		
Number of subjects with a remission, n (%) [2]	5 (20.0)	4 (23.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.18
95% CI for the RR		(0.368, 3.758)
p-value for RR		0.7839

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 15		
Number of subjects with a remission, n (%) [2]	8 (32.0)	7 (41.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.29
95% CI for the RR		(0.575, 2.880)
p-value for RR		0.5397
Day 21		
Number of subjects with a remission, n (%) [2]	8 (32.0)	6 (35.3)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.10
95% CI for the RR		(0.466, 2.608)
p-value for RR		0.8234

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 45		
Number of subjects with a remission, n (%) [2]	8 (32.0)	8 (47.1)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.47
95% CI for the RR		(0.686, 3.151)
p-value for RR		0.3212

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-201B - ITT population

Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 3		
Number of subjects with a remission, n (%) [2]	4 (8.0)	10 (16.9)
Number of subjects with missing evaluation, n (%)	1 (2.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.12
95% CI for the RR		(0.708, 6.343)
p-value for RR		0.1796
Day 8		
Number of subjects with a remission, n (%) [2]	9 (18.0)	20 (33.9)
Number of subjects with missing evaluation, n (%)	1 (2.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.88
95% CI for the RR		(0.944, 3.757)
p-value for RR		0.0724

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 15		
Number of subjects with a remission, n (%) [2]	9 (18.0)	26 (44.1)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.45
95% CI for the RR		(1.268, 4.726)
p-value for RR		0.0076
Day 21		
Number of subjects with a remission, n (%) [2]	13 (26.0)	25 (42.4)
Number of subjects with missing evaluation, n (%)	2 (4.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.63
95% CI for the RR		(0.936, 2.837)
p-value for RR		0.0842

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 45		
Number of subjects with a remission, n (%) [2]	13 (26.0)	31 (52.5)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.02
95% CI for the RR		(1.193, 3.422)
p-value for RR		0.0089

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.1.3.1 .2 .2 .2 Schwere der Erkrankung

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 3		
Number of subjects with a remission, n (%) [2]	1 (4.5)	6 (20.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		4.844
95% CI for the RR		(0.579, 40.535)
p-value for RR		0.1455
Day 8		
Number of subjects with a remission, n (%) [2]	5 (22.7)	6 (20.0)
Number of subjects with missing evaluation, n (%)	0	1 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.944
95% CI for the RR		(0.332, 2.685)
p-value for RR		0.9145

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 15		
Number of subjects with a remission, n (%) [2]	6 (27.3)	12 (40.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.638
95% CI for the RR		(0.730, 3.674)
p-value for RR		0.2312
Day 21		
Number of subjects with a remission, n (%) [2]	7 (31.8)	10 (33.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.153
95% CI for the RR		(0.528, 2.517)
p-value for RR		0.7205

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 45		
Number of subjects with a remission, n (%) [2]	7 (31.8)	15 (50.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.766
95% CI for the RR		(0.856, 3.643)
p-value for RR		0.1239

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 3		
Number of subjects with a remission, n (%) [2]	3 (5.7)	8 (17.4)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.088
95% CI for the RR		(0.870, 10.967)
p-value for RR		0.0812
Day 8		
Number of subjects with a remission, n (%) [2]	9 (17.0)	18 (39.1)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.266
95% CI for the RR		(1.115, 4.605)
p-value for RR		0.0238

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 15		
Number of subjects with a remission, n (%) [2]	11 (20.8)	21 (45.7)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.189
95% CI for the RR		(1.199, 3.994)
p-value for RR		0.0107
Day 21		
Number of subjects with a remission, n (%) [2]	14 (26.4)	21 (45.7)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.774
95% CI for the RR		(1.022, 3.076)
p-value for RR		0.0414

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 45		
Number of subjects with a remission, n (%) [2]	14 (26.4)	24 (52.2)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.028
95% CI for the RR		(1.200, 3.430)
p-value for RR		0.0083

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.1.3.1 .2 .2 .3 Abstammung

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-201B - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 3		
Number of subjects with a remission, n (%) [2]	1 (3.1)	1 (3.2)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.899
95% CI for the RR		(0.051, 15.761)
p-value for RR		0.9417
Day 8		
Number of subjects with a remission, n (%) [2]	7 (21.9)	9 (29.0)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.208
95% CI for the RR		(0.498, 2.932)
p-value for RR		0.6764

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-201B - ITT population

Page: 2 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 15		
Number of subjects with a remission, n (%) [2]	6 (18.8)	15 (48.4)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.375
95% CI for the RR		(1.030, 5.475)
p-value for RR		0.0423
Day 21		
Number of subjects with a remission, n (%) [2]	8 (25.0)	11 (35.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.289
95% CI for the RR		(0.580, 2.864)
p-value for RR		0.5331

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-201B - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 45		
Number of subjects with a remission, n (%) [2]	8 (25.0)	15 (48.4)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.802
95% CI for the RR		(0.894, 3.635)
p-value for RR		0.0999

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-201B - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 3		
Number of subjects with a remission, n (%) [2]	3 (7.5)	13 (29.5)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		3.884
95% CI for the RR		(1.219, 12.376)
p-value for RR		0.0217
Day 8		
Number of subjects with a remission, n (%) [2]	7 (17.5)	15 (34.1)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.913
95% CI for the RR		(0.876, 4.181)
p-value for RR		0.1038

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-201B - ITT population

Page: 5 of 6

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 15		
Number of subjects with a remission, n (%) [2]	11 (27.5)	17 (38.6)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.395
95% CI for the RR		(0.758, 2.568)
p-value for RR		0.2850
Day 21		
Number of subjects with a remission, n (%) [2]	12 (30.0)	20 (45.5)
Number of subjects with missing evaluation, n (%)	1 (2.5)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.519
95% CI for the RR		(0.849, 2.718)
p-value for RR		0.1594

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-201B - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 45		
Number of subjects with a remission, n (%) [2]	12 (30.0)	23 (52.3)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.746
95% CI for the RR		(1.011, 3.015)
p-value for RR		0.0457

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.1.3.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 3		
Number of subjects with a remission, n (%) [2]	2 (15.4)	5 (31.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.004
95% CI for the RR		(0.455, 8.831)
p-value for RR		0.3584
Day 8		
Number of subjects with a remission, n (%) [2]	3 (23.1)	5 (31.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.336
95% CI for the RR		(0.384, 4.651)
p-value for RR		0.6492

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 15		
Number of subjects with a remission, n (%) [2]	5 (38.5)	9 (56.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.443
95% CI for the RR		(0.628, 3.312)
p-value for RR		0.3873
Day 21		
Number of subjects with a remission, n (%) [2]	3 (23.1)	8 (50.0)
Number of subjects with missing evaluation, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.137
95% CI for the RR		(0.693, 6.595)
p-value for RR		0.1864

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 45		
Number of subjects with a remission, n (%) [2]	4 (30.8)	10 (62.5)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.004
95% CI for the RR		(0.801, 5.010)
p-value for RR		0.1372

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 3		
Number of subjects with a remission, n (%) [2]	2 (3.2)	9 (15.0)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		4.516
95% CI for the RR		(1.021, 19.982)
p-value for RR		0.0469
Day 8		
Number of subjects with a remission, n (%) [2]	11 (17.7)	19 (31.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.734
95% CI for the RR		(0.895, 3.359)
p-value for RR		0.1030

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 15		
Number of subjects with a remission, n (%) [2]	12 (19.4)	24 (40.0)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.007
95% CI for the RR		(1.097, 3.672)
p-value for RR		0.0237
Day 21		
Number of subjects with a remission, n (%) [2]	18 (29.0)	23 (38.3)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.282
95% CI for the RR		(0.768, 2.140)
p-value for RR		0.3412

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 45		
Number of subjects with a remission, n (%) [2]	17 (27.4)	29 (48.3)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.712
95% CI for the RR		(1.054, 2.782)
p-value for RR		0.0299

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.1.3.1 .2 .2 .5 BMI

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 3		
Number of subjects with a remission, n (%) [2]	1 (4.8)	3 (23.1)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		4.85
95% CI for the RR		(0.562, 41.807)
p-value for RR		0.1512
Day 8		
Number of subjects with a remission, n (%) [2]	4 (19.0)	4 (30.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.62
95% CI for the RR		(0.486, 5.368)
p-value for RR		0.4338

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 15		
Number of subjects with a remission, n (%) [2]	6 (28.6)	5 (38.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.35
95% CI for the RR		(0.513, 3.531)
p-value for RR		0.5458
Day 21		
Number of subjects with a remission, n (%) [2]	3 (14.3)	6 (46.2)
Number of subjects with missing evaluation, n (%)	2 (9.5)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		3.23
95% CI for the RR		(0.972, 10.737)
p-value for RR		0.0556

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 45		
Number of subjects with a remission, n (%) [2]	5 (23.8)	8 (61.5)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.58
95% CI for the RR		(1.075, 6.216)
p-value for RR		0.0339

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 3		
Number of subjects with a remission, n (%) [2]	0	7 (33.3)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		14.32
95% CI for the RR		(0.871, 235.355)
p-value for RR		0.0624
Day 8		
Number of subjects with a remission, n (%) [2]	3 (15.0)	11 (52.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		3.49
95% CI for the RR		(1.139, 10.704)
p-value for RR		0.0287

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 15		
Number of subjects with a remission, n (%) [2]	1 (5.0)	10 (47.6)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		9.52
95% CI for the RR		(1.338, 67.768)
p-value for RR		0.0244
Day 21		
Number of subjects with a remission, n (%) [2]	6 (30.0)	12 (57.1)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.90
95% CI for the RR		(0.886, 4.094)
p-value for RR		0.0988

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 45		
Number of subjects with a remission, n (%) [2]	7 (35.0)	14 (66.7)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.90
95% CI for the RR		(0.975, 3.720)
p-value for RR		0.0592

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 3		
Number of subjects with a remission, n (%) [2]	3 (8.8)	4 (9.5)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.08
95% CI for the RR		(0.259, 4.497)
p-value for RR		0.9165
Day 8		
Number of subjects with a remission, n (%) [2]	7 (20.6)	9 (21.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.04
95% CI for the RR		(0.433, 2.505)
p-value for RR		0.9289

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 15		
Number of subjects with a remission, n (%) [2]	10 (29.4)	18 (42.9)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.46
95% CI for the RR		(0.778, 2.728)
p-value for RR		0.2392
Day 21		
Number of subjects with a remission, n (%) [2]	12 (35.3)	13 (31.0)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.88
95% CI for the RR		(0.462, 1.665)
p-value for RR		0.6883

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 45		
Number of subjects with a remission, n (%) [2]	9 (26.5)	17 (40.5)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.53
95% CI for the RR		(0.783, 2.987)
p-value for RR		0.2138

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.1.3.1 .2 .2 .6 Beginn der PPD

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 3		
Number of subjects with a remission, n (%) [2]	2 (6.3)	4 (12.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.004
95% CI for the RR		(0.401, 10.022)
p-value for RR		0.3974
Day 8		
Number of subjects with a remission, n (%) [2]	6 (18.8)	12 (37.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.015
95% CI for the RR		(0.864, 4.698)
p-value for RR		0.1049

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 15		
Number of subjects with a remission, n (%) [2]	6 (18.8)	16 (50.0)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.729
95% CI for the RR		(1.229, 6.060)
p-value for RR		0.0136
Day 21		
Number of subjects with a remission, n (%) [2]	10 (31.3)	15 (46.9)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.570
95% CI for the RR		(0.829, 2.973)
p-value for RR		0.1664

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 45		
Number of subjects with a remission, n (%) [2]	9 (28.1)	20 (62.5)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.255
95% CI for the RR		(1.225, 4.154)
p-value for RR		0.0090

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 3		
Number of subjects with a remission, n (%) [2]	2 (4.7)	10 (22.7)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		4.680
95% CI for the RR		(1.099, 19.930)
p-value for RR		0.0368
Day 8		
Number of subjects with a remission, n (%) [2]	8 (18.6)	12 (27.3)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.392
95% CI for the RR		(0.635, 3.054)
p-value for RR		0.4093

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 15		
Number of subjects with a remission, n (%) [2]	11 (25.6)	17 (38.6)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.464
95% CI for the RR		(0.780, 2.748)
p-value for RR		0.2349
Day 21		
Number of subjects with a remission, n (%) [2]	11 (25.6)	16 (36.4)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.349
95% CI for the RR		(0.713, 2.553)
p-value for RR		0.3575

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 45		
Number of subjects with a remission, n (%) [2]	12 (27.9)	19 (43.2)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.488
95% CI for the RR		(0.829, 2.668)
p-value for RR		0.1827

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.1.3.1 .2 .2 .7 PPD in der Familie

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 3		
Number of subjects with a remission, n (%) [2]	0	1 (10.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.137, 65.903)
p-value for RR		0.4858
Day 8		
Number of subjects with a remission, n (%) [2]	1 (10.0)	2 (20.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.00
95% CI for the RR		(0.214, 18.687)
p-value for RR		0.5432

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 15		
Number of subjects with a remission, n (%) [2]	2 (20.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.00
95% CI for the RR		(0.467, 8.557)
p-value for RR		0.3500
Day 21		
Number of subjects with a remission, n (%) [2]	2 (20.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.00
95% CI for the RR		(0.467, 8.557)
p-value for RR		0.3500

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 45		
Number of subjects with a remission, n (%) [2]	1 (10.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		4.00
95% CI for the RR		(0.537, 29.805)
p-value for RR		0.1761

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 3		
Number of subjects with a remission, n (%) [2]	4 (6.2)	13 (19.7)
Number of subjects with missing evaluation, n (%)	1 (1.5)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.20
95% CI for the RR		(1.101, 9.304)
p-value for RR		0.0326
Day 8		
Number of subjects with a remission, n (%) [2]	13 (20.0)	22 (33.3)
Number of subjects with missing evaluation, n (%)	1 (1.5)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.67
95% CI for the RR		(0.920, 3.019)
p-value for RR		0.0919

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 15		
Number of subjects with a remission, n (%) [2]	15 (23.1)	29 (43.9)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.90
95% CI for the RR		(1.131, 3.205)
p-value for RR		0.0154
Day 21		
Number of subjects with a remission, n (%) [2]	19 (29.2)	27 (40.9)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.40
95% CI for the RR		(0.869, 2.254)
p-value for RR		0.1669

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 45		
Number of subjects with a remission, n (%) [2]	20 (30.8)	35 (53.0)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.72
95% CI for the RR		(1.122, 2.648)
p-value for RR		0.0130

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.1.3.1 .2 .2 .8 PPD in der Anamnese

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 6

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 3		
Number of subjects with a remission, n (%) [2]	3 (5.1)	11 (16.7)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.324
95% CI for the RR		(0.974, 11.352)
p-value for RR		0.0552
Day 8		
Number of subjects with a remission, n (%) [2]	13 (22.0)	19 (28.8)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.325
95% CI for the RR		(0.715, 2.457)
p-value for RR		0.3710

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-201B - ITT population

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 15		
Number of subjects with a remission, n (%) [2]	15 (25.4)	29 (43.9)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.745
95% CI for the RR		(1.045, 2.916)
p-value for RR		0.0334
Day 21		
Number of subjects with a remission, n (%) [2]	17 (28.8)	26 (39.4)
Number of subjects with missing evaluation, n (%)	1 (1.7)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.403
95% CI for the RR		(0.846, 2.327)
p-value for RR		0.1889

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 45		
Number of subjects with a remission, n (%) [2]	17 (28.8)	34 (51.5)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.821
95% CI for the RR		(1.141, 2.906)
p-value for RR		0.0119

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 3		
Number of subjects with a remission, n (%) [2]	1 (6.3)	3 (30.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.643
95% CI for the RR		(0.429, 30.926)
p-value for RR		0.2361
Day 8		
Number of subjects with a remission, n (%) [2]	1 (6.3)	5 (50.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		5.752
95% CI for the RR		(0.797, 41.521)
p-value for RR		0.0828

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 15		
Number of subjects with a remission, n (%) [2]	2 (12.5)	4 (40.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.331
95% CI for the RR		(0.482, 11.279)
p-value for RR		0.2928
Day 21		
Number of subjects with a remission, n (%) [2]	4 (25.0)	5 (50.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.399
95% CI for the RR		(0.426, 4.596)
p-value for RR		0.5805

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 45		
Number of subjects with a remission, n (%) [2]	4 (25.0)	5 (50.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.598
95% CI for the RR		(0.522, 4.886)
p-value for RR		0.4115

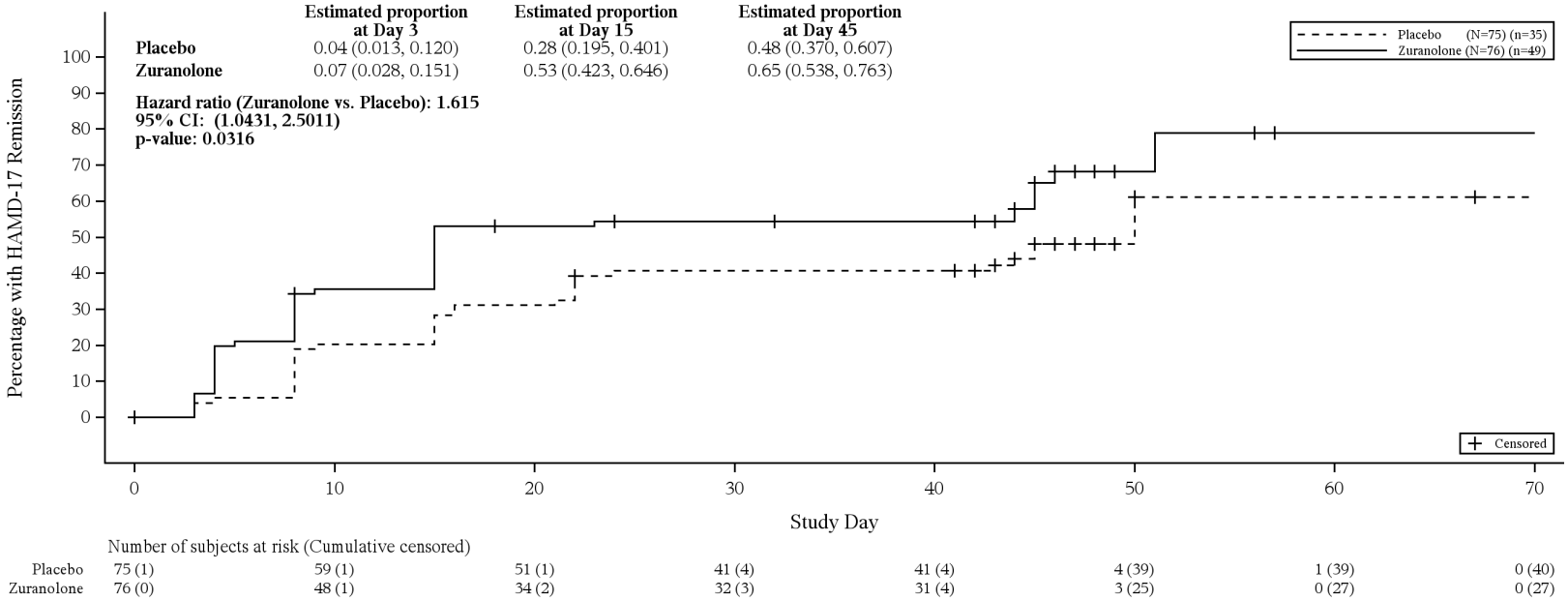
NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAMD-17 remission (defined as HAMD-17 total score <=7). Missing HAMD-17 total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hamd-remi-201-by.sas:t-hamd-remi-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.1.3.2 TTE-Analysen

4.1.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.
NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-ovr.sas:f-hamd-remi-tte-201-ovr-itta.rtf **Run Date:** 16DEC2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	35 (46.7)	49 (64.5)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 22.0)	8.0 (4.0 , 9.0)
50th percentile - median (95% CI)	50.0 (22.0, NE)	15.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	51.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.615
95% CI for the HR		(1.0431 , 2.5011)
p-value for the HR		0.0316

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-ovr.sas:t-hamd-remi-tte-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.1.3.2 .2 Subgruppen

4.1.3.2 .2 .1 Interaktionstest

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	35 (46.7)	49 (64.5)	
Age Group (years)			
18 - 24, n / N (%)	13/25 (52.0)	13/17 (76.5)	0.6607
25 - 45, n / N (%)	22/50 (44.0)	36/59 (61.0)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	11/22 (50.0)	18/30 (60.0)	0.6392
>=28, n / N (%)	24/53 (45.3)	31/46 (67.4)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	15/32 (46.9)	20/31 (64.5)	0.6206
White, n / N (%)	19/40 (47.5)	28/44 (63.6)	
Antidepressant Use at Baseline			
Yes, n / N (%)	7/13 (53.8)	12/16 (75.0)	0.6300
No, n / N (%)	28/62 (45.2)	37/60 (61.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-int.sas:t-hamd-remi-tte-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	9/21 (42.9)	11/13 (84.6)	0.9036(a)
25-29.9, n / N (%)	9/20 (45.0)	15/21 (71.4)	0.1292(b)
>=30, n / N (%)	17/34 (50.0)	23/42 (54.8)	0.0853(c)
Onset of PPD			
3rd Trimester, n / N (%)	16/32 (50.0)	23/32 (71.9)	0.8973
Postpartum, n / N (%)	19/43 (44.2)	26/44 (59.1)	
Family History of PPD			
Yes, n / N (%)	4/10 (40.0)	5/10 (50.0)	0.6581
No/Unknown, n / N (%)	31/65 (47.7)	44/66 (66.7)	
History of PPD			
1st Episode, n / N (%)	31/59 (52.5)	43/66 (65.2)	0.4425
Recurrent Episode, n / N (%)	4/16 (25.0)	6/10 (60.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	5/8 (62.5)	7/10 (70.0)	NA
>=20, n / N (%)	30/67 (44.8)	42/66 (63.6)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-int.sas:t-hamd-remi-tte-201-int-itta.rtf **Run Date:** 29JUL2025

4.1.3.2 .2 .2 Subgruppenanalysen

4.1.3.2 .2 .2 .1 Alter

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	13 (52.0)	13 (76.5)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 22.0)	5.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	15.0 (4.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	51.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.977
95% CI for the HR		(0.9055 , 4.3184)
p-value for the HR		0.0871

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-201B - ITT population

Page: 2 of 2

Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	22 (44.0)	36 (61.0)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	16.0 (8.0 , 24.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	50.0 (22.0, NE)	15.0 (15.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	NE (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.540
95% CI for the HR		(0.8997 , 2.6373)
p-value for the HR		0.1154

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.1.3.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	11 (50.0)	18 (60.0)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 43.0)	5.0 (4.0 , 15.0)
50th percentile - median (95% CI)	50.0 (15.0, NE)	44.0 (15.0, NE)
75th percentile - Q3 (95% CI)	50.0 (NE, NE)	NE (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.512
95% CI for the HR		(0.7018 , 3.2562)
p-value for the HR		0.2912

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	24 (45.3)	31 (67.4)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.5 (8.0 , 22.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	NE (22.0, NE)	15.0 (8.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	51.0 (44.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.749
95% CI for the HR		(1.0224 , 2.9926)
p-value for the HR		0.0413

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.1.3.2 .2 .2 .3 Abstammung

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	15 (46.9)	20 (64.5)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 22.0)	8.0 (5.0 , 15.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	15.0 (8.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.476
95% CI for the HR		(0.7280 , 2.9920)
p-value for the HR		0.2803

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-201B - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	19 (47.5)	28 (63.6)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 24.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	50.0 (22.0, NE)	15.0 (8.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	51.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.693
95% CI for the HR		(0.9405 , 3.0491)
p-value for the HR		0.0792

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.1.3.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	7 (53.8)	12 (75.0)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 45.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (8.0, NE)	15.0 (4.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (16.0, NE)	45.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.826
95% CI for the HR		(0.7140 , 4.6681)
p-value for the HR		0.2089

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	28 (45.2)	37 (61.7)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 22.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	50.0 (22.0, NE)	19.0 (15.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	51.0 (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.528
95% CI for the HR		(0.9296 , 2.5110)
p-value for the HR		0.0945

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.1.3.2 .2 .2 .5 BMI

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	9 (42.9)	11 (84.6)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 44.0)	8.0 (3.0 , 23.0)
50th percentile - median (95% CI)	NE (15.0, NE)	23.0 (4.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	45.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.073
95% CI for the HR		(1.1663 , 8.0991)
p-value for the HR		0.0231

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	9 (45.0)	15 (71.4)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	22.0 (8.0 , 50.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	50.0 (22.0, NE)	9.0 (4.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.769
95% CI for the HR		(1.1695 , 6.5576)
p-value for the HR		0.0206

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

Page: 3 of 3

BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	17 (50.0)	23 (54.8)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 22.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	45.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	51.0 (51.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.060
95% CI for the HR		(0.5617 , 2.0015)
p-value for the HR		0.8567

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.1.3.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	16 (50.0)	23 (71.9)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 22.0)	8.0 (3.0 , 9.0)
50th percentile - median (95% CI)	45.0 (21.0, NE)	15.0 (8.0 , 45.0)
75th percentile - Q3 (95% CI)	50.0 (50.0, NE)	51.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.811
95% CI for the HR		(0.9274 , 3.5382)
p-value for the HR		0.0820

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	19 (44.2)	26 (59.1)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 24.0)	4.5 (4.0 , 15.0)
50th percentile - median (95% CI)	NE (22.0, NE)	23.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.528
95% CI for the HR		(0.8414 , 2.7757)
p-value for the HR		0.1637

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.1.3.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	4 (40.0)	5 (50.0)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	16.0 (8.0, NE)	15.0 (4.0 , 44.0)
50th percentile - median (95% CI)	NE (8.0, NE)	44.0 (4.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (44.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.009
95% CI for the HR		(0.2335 , 4.3583)
p-value for the HR		0.9905

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	31 (47.7)	44 (66.7)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 22.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	50.0 (22.0, NE)	15.0 (9.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	51.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.658
95% CI for the HR		(1.0389 , 2.6450)
p-value for the HR		0.0340

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.1.3.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	31 (52.5)	43 (65.2)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 22.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	45.0 (22.0, NE)	15.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	51.0 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.486
95% CI for the HR		(0.9328 , 2.3668)
p-value for the HR		0.0955

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	4 (25.0)	6 (60.0)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	21.0 (4.0, NE)	4.0 (3.0 , 44.0)
50th percentile - median (95% CI)	NE (15.0, NE)	26.0 (3.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.025
95% CI for the HR		(0.4949 , 8.2871)
p-value for the HR		0.3263

NOTE 1: HAMD-17 remission is defined as having a HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects with no remission are censored at the day of the last available HAMD-17 evaluation.

[1] Number of subjects with non-missing HAMD-17 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAMD-17 remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAMD-17 total score, and treatment.

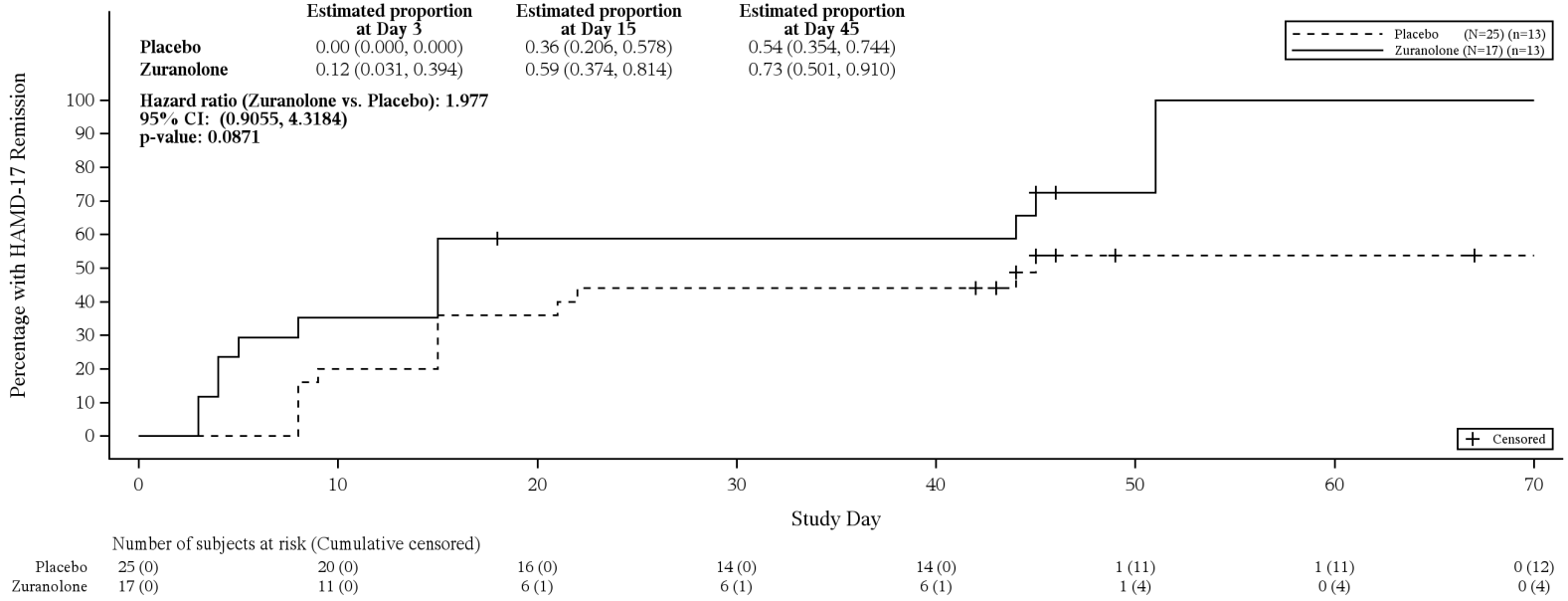
Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-201-by.sas:t-hamd-remi-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.1.3.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

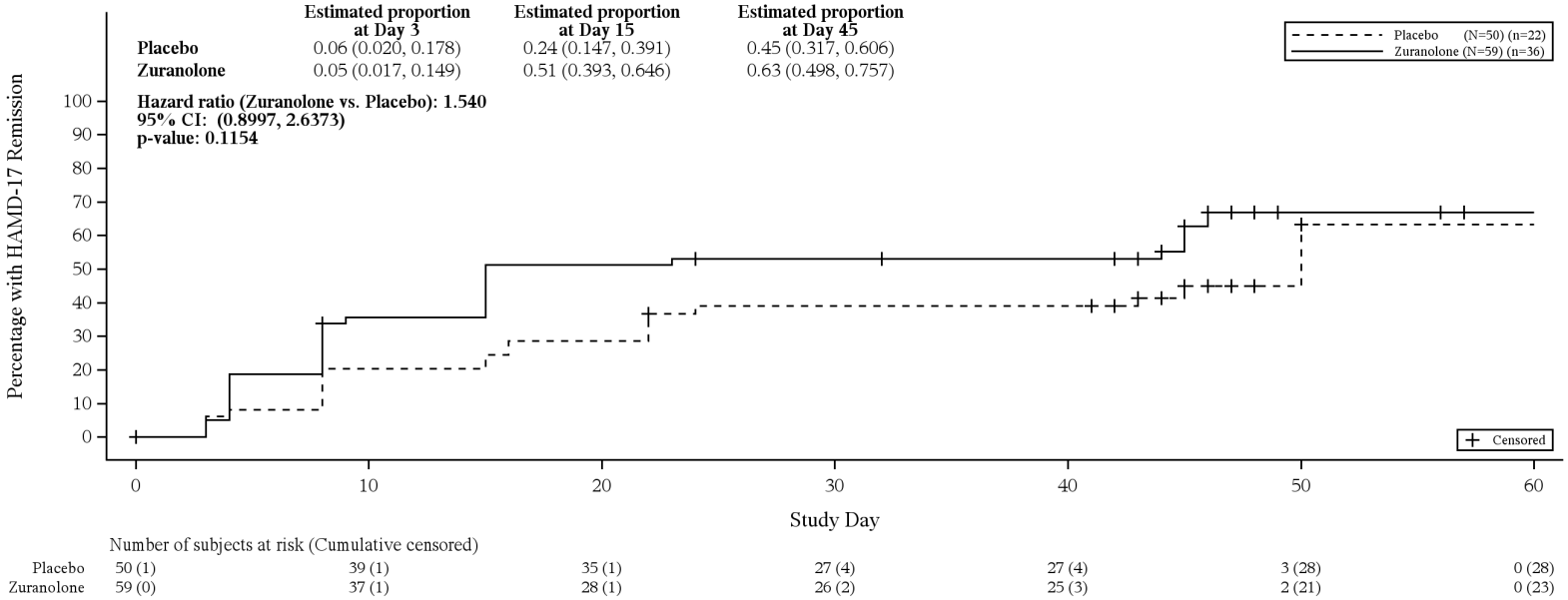
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

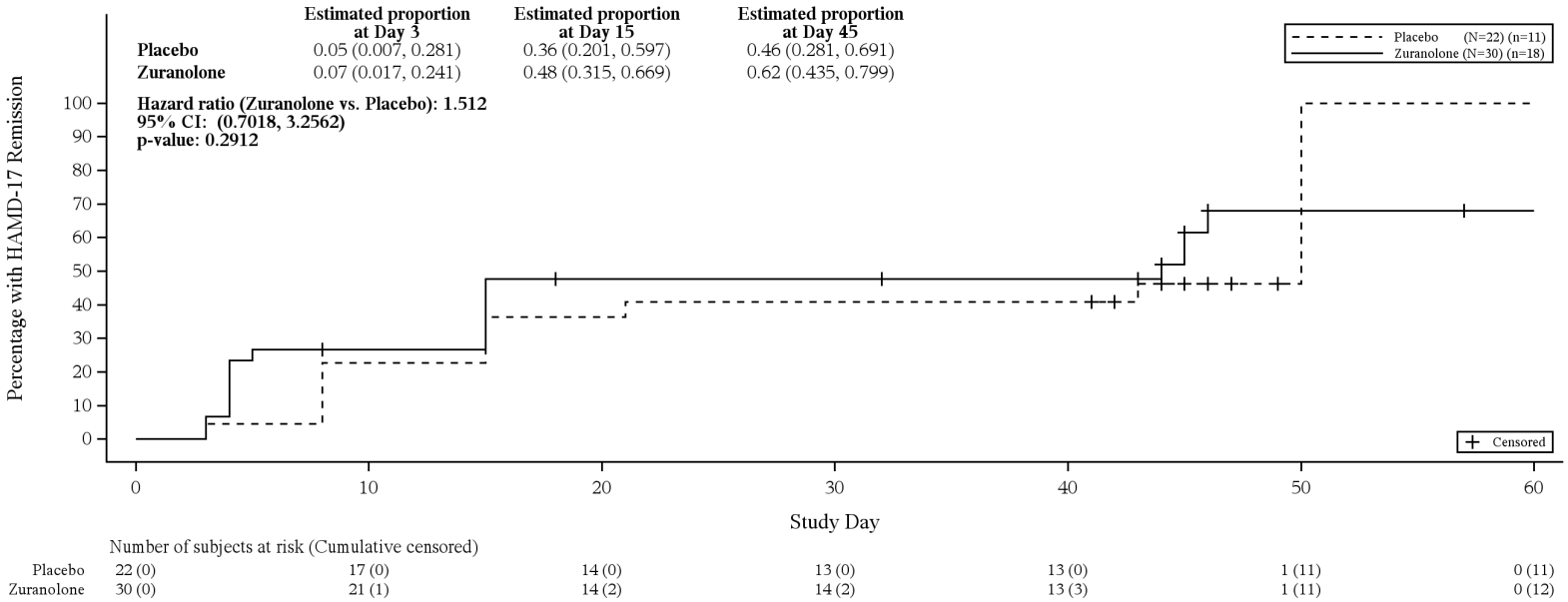
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

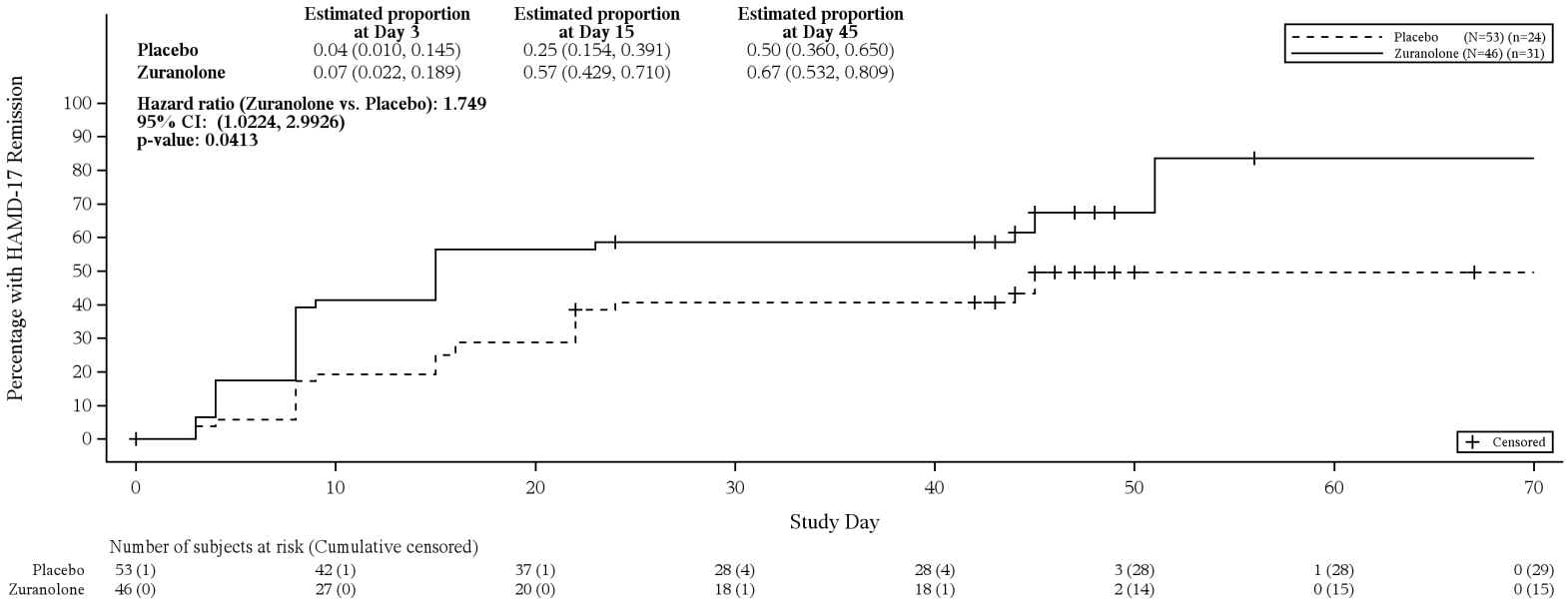
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

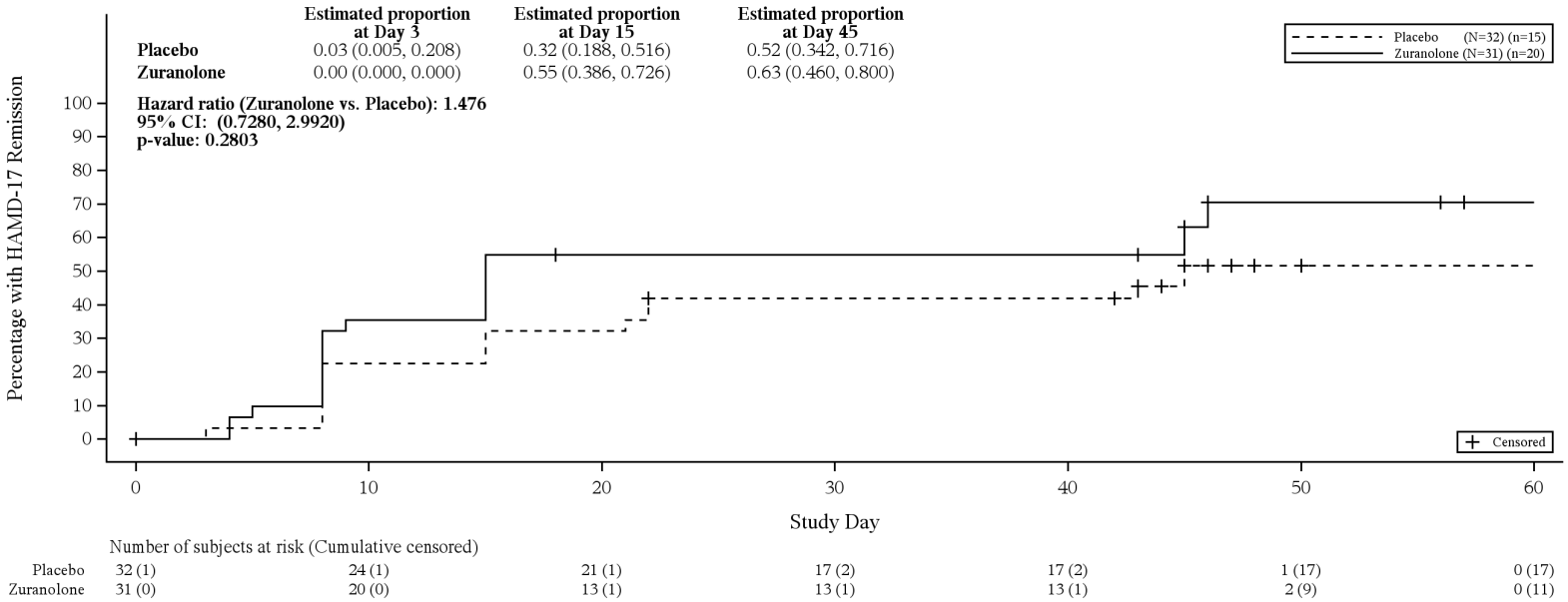
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

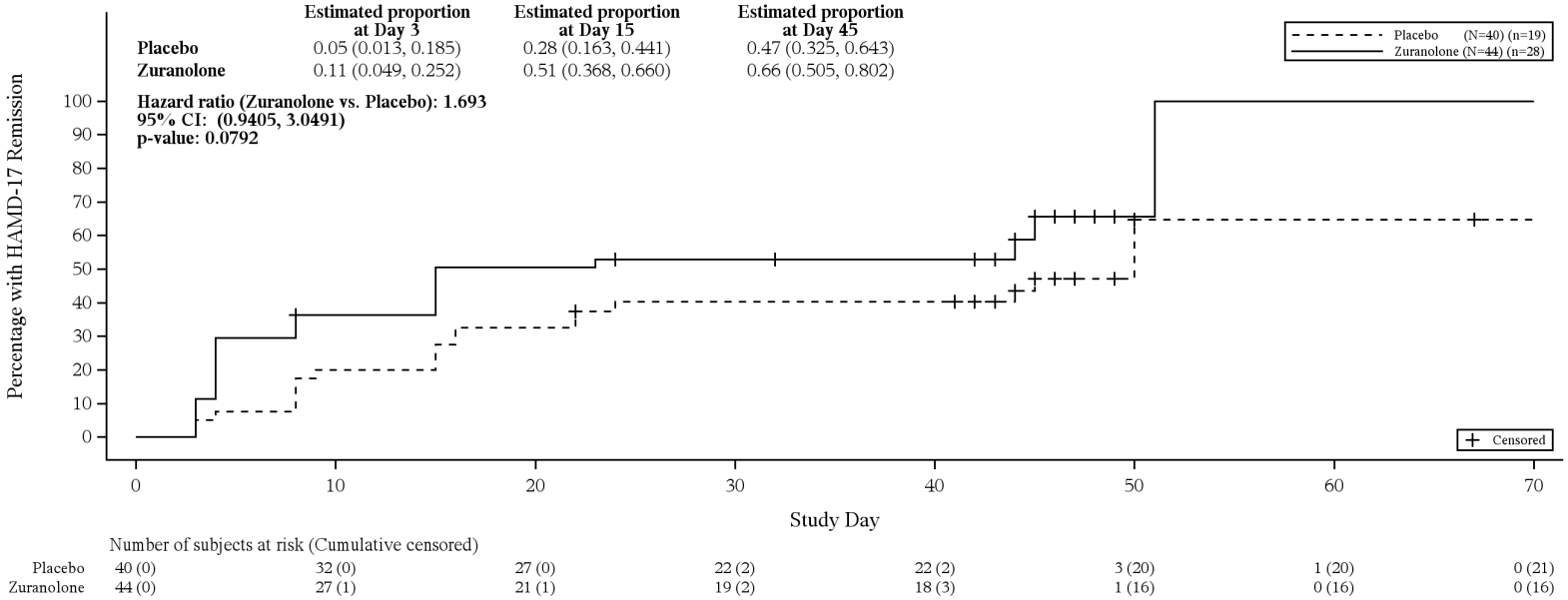
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

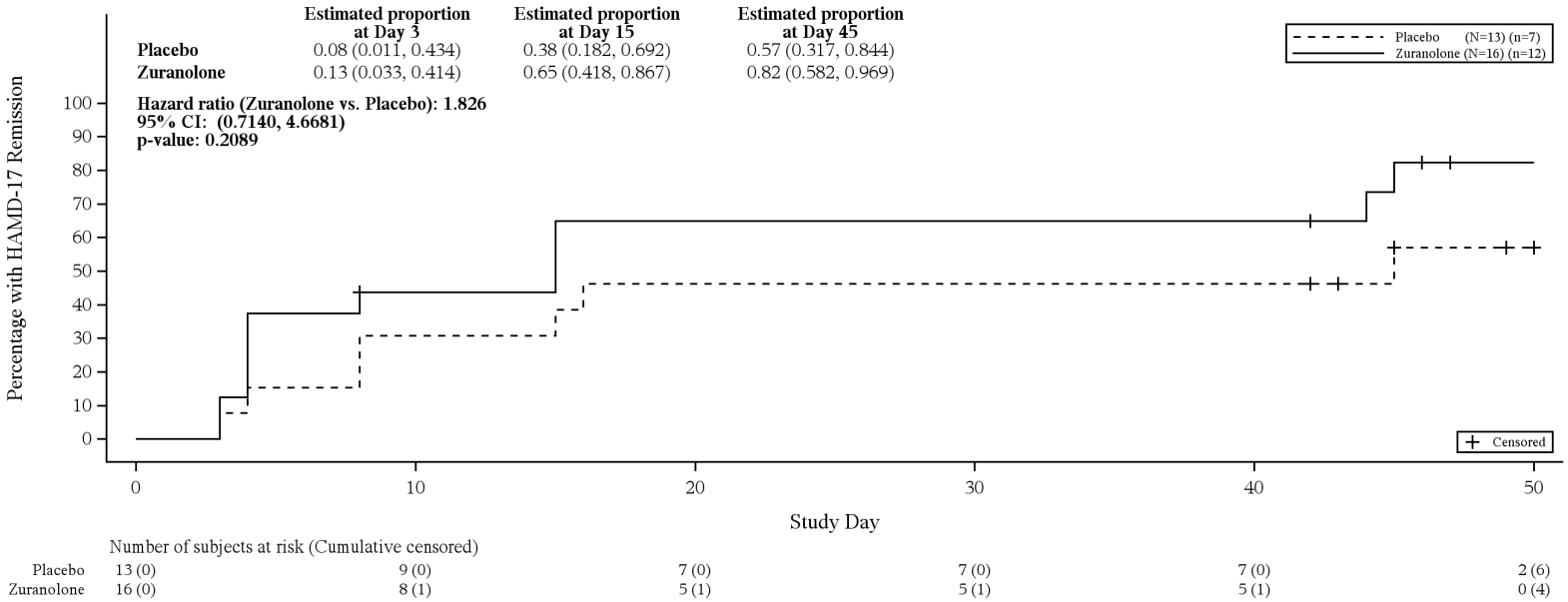
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

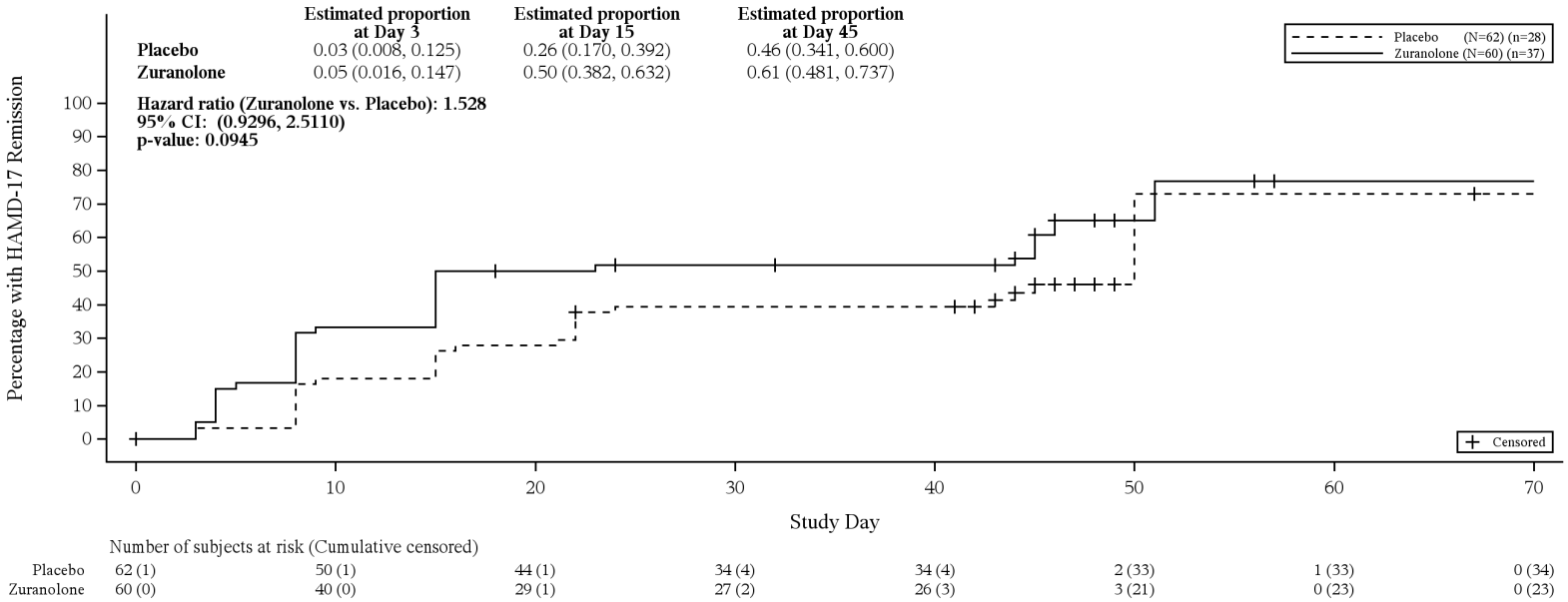
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

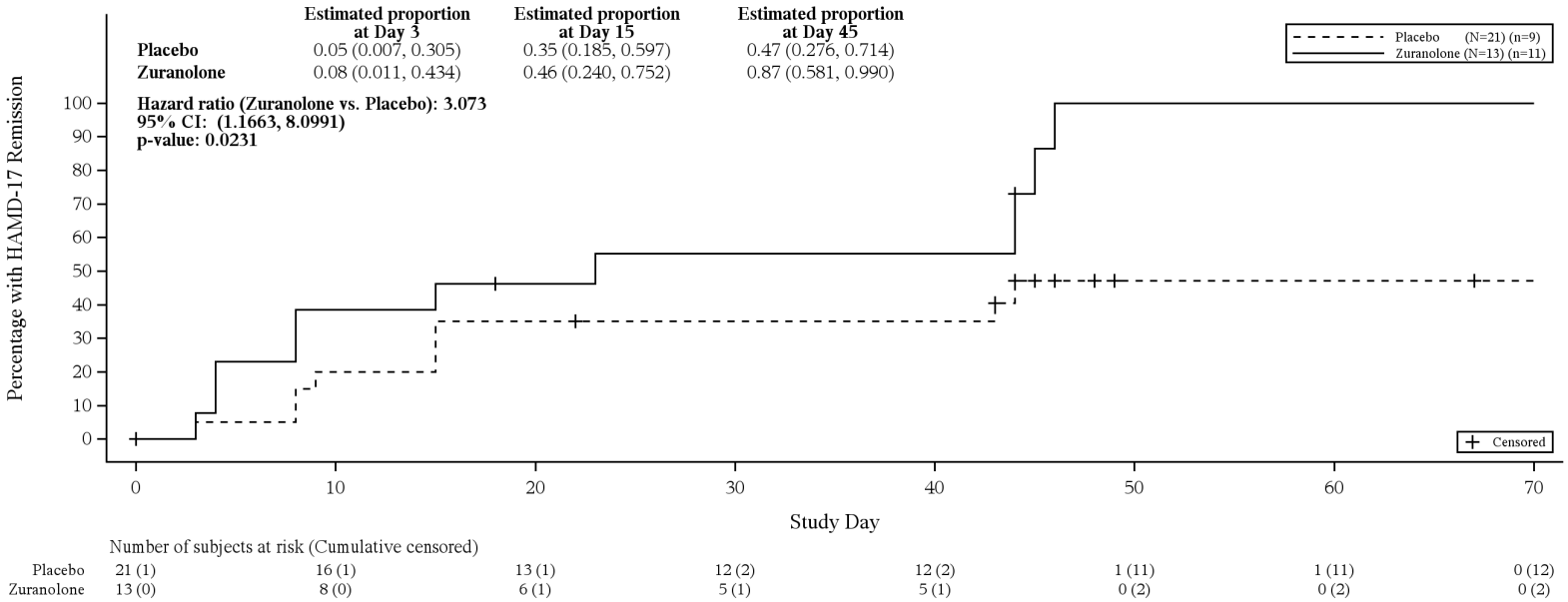
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 9 of 17

BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

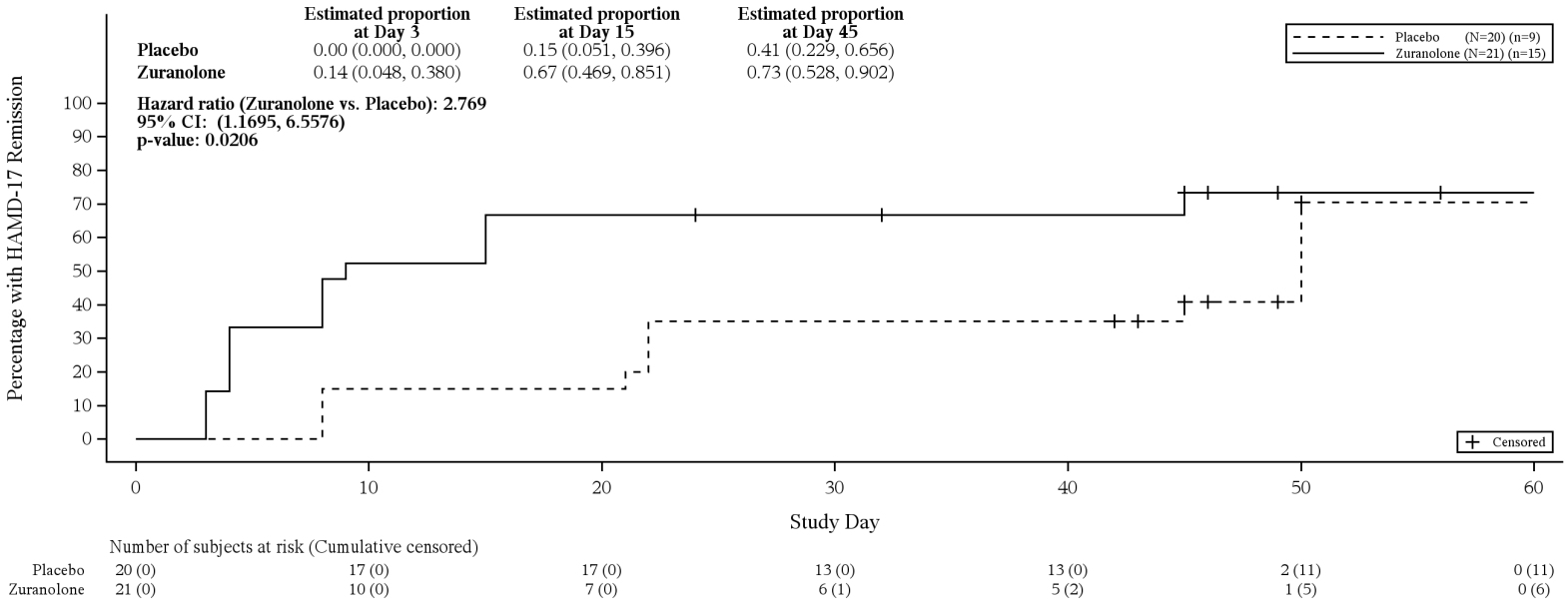
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 10 of 17

BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

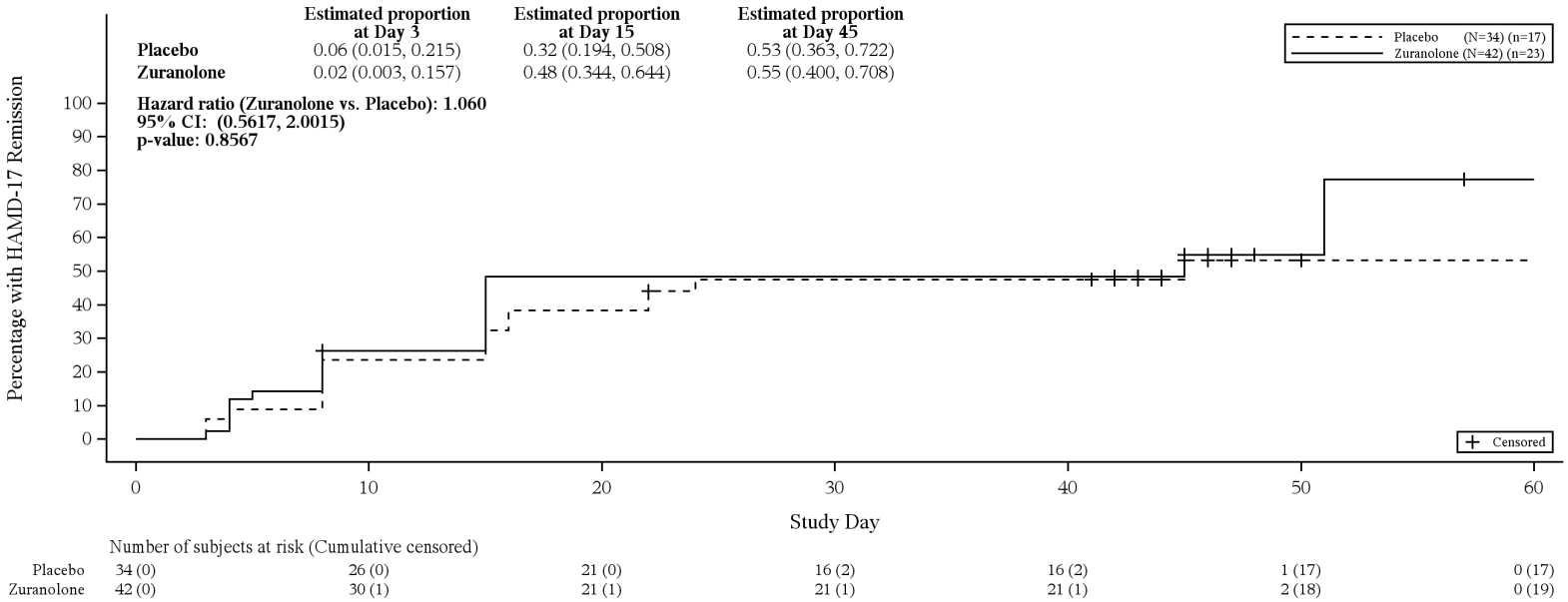
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

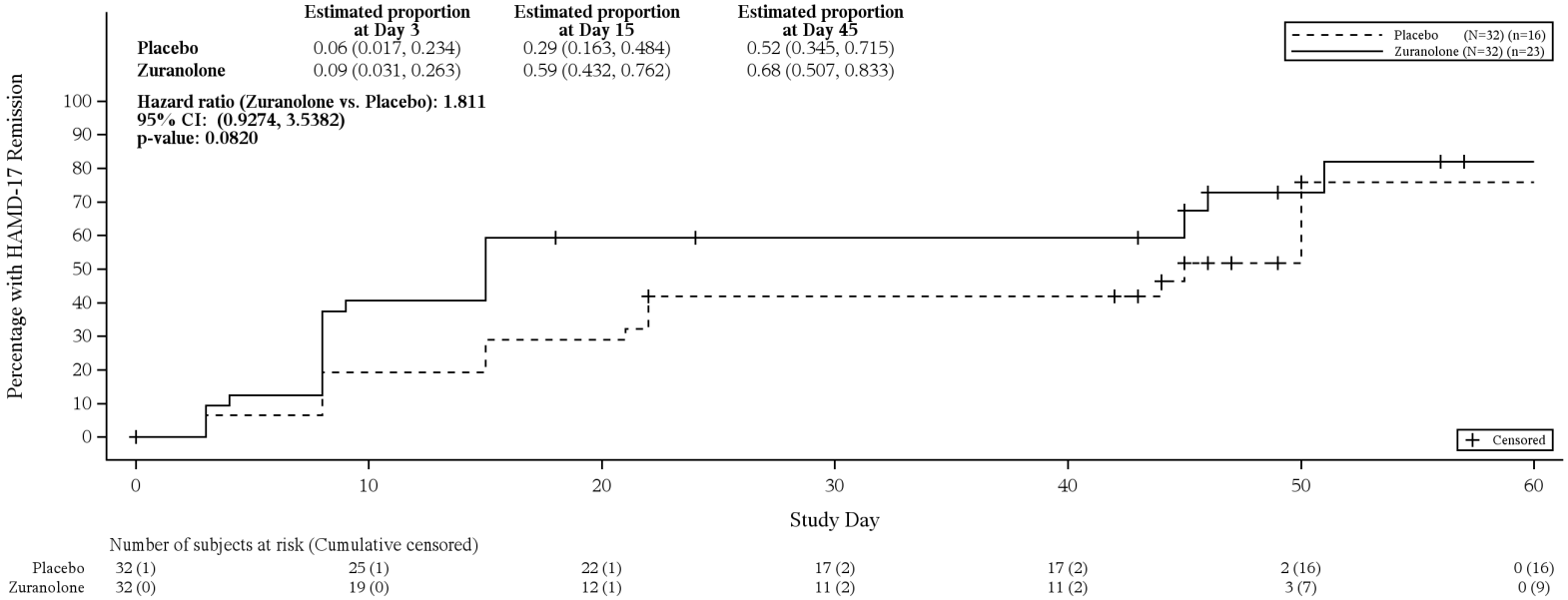
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

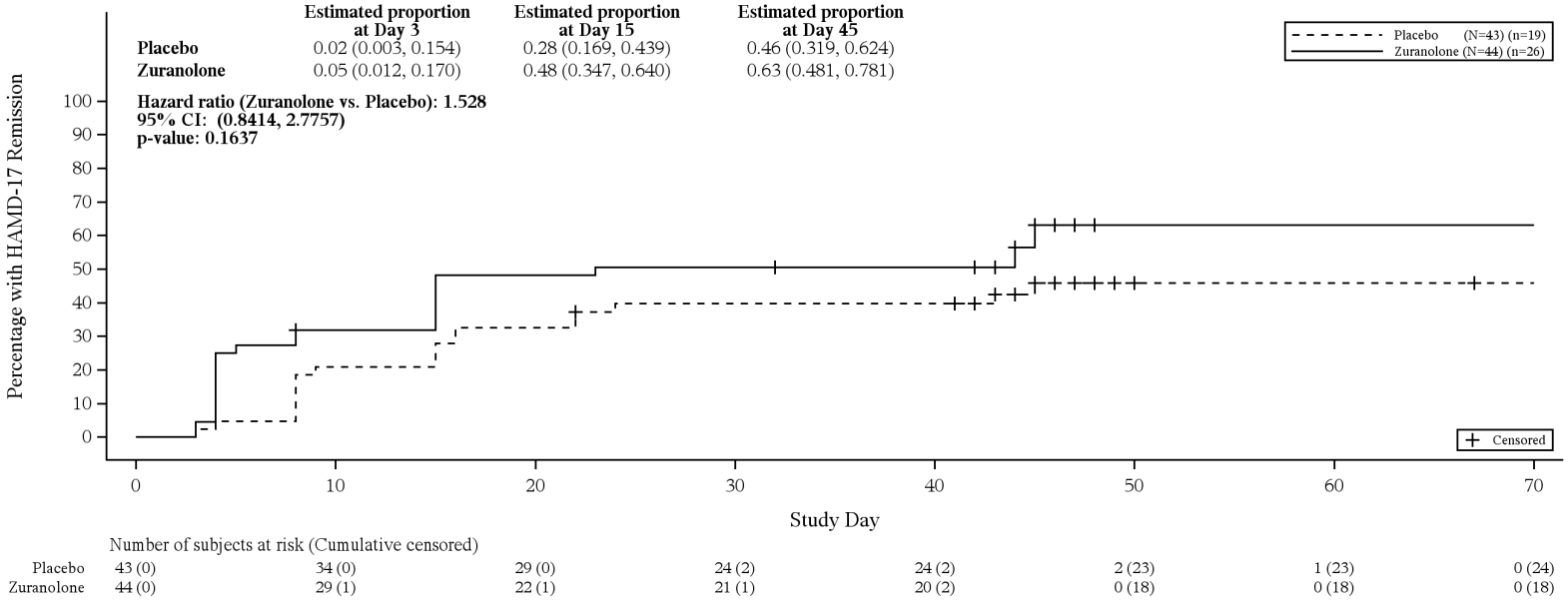
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

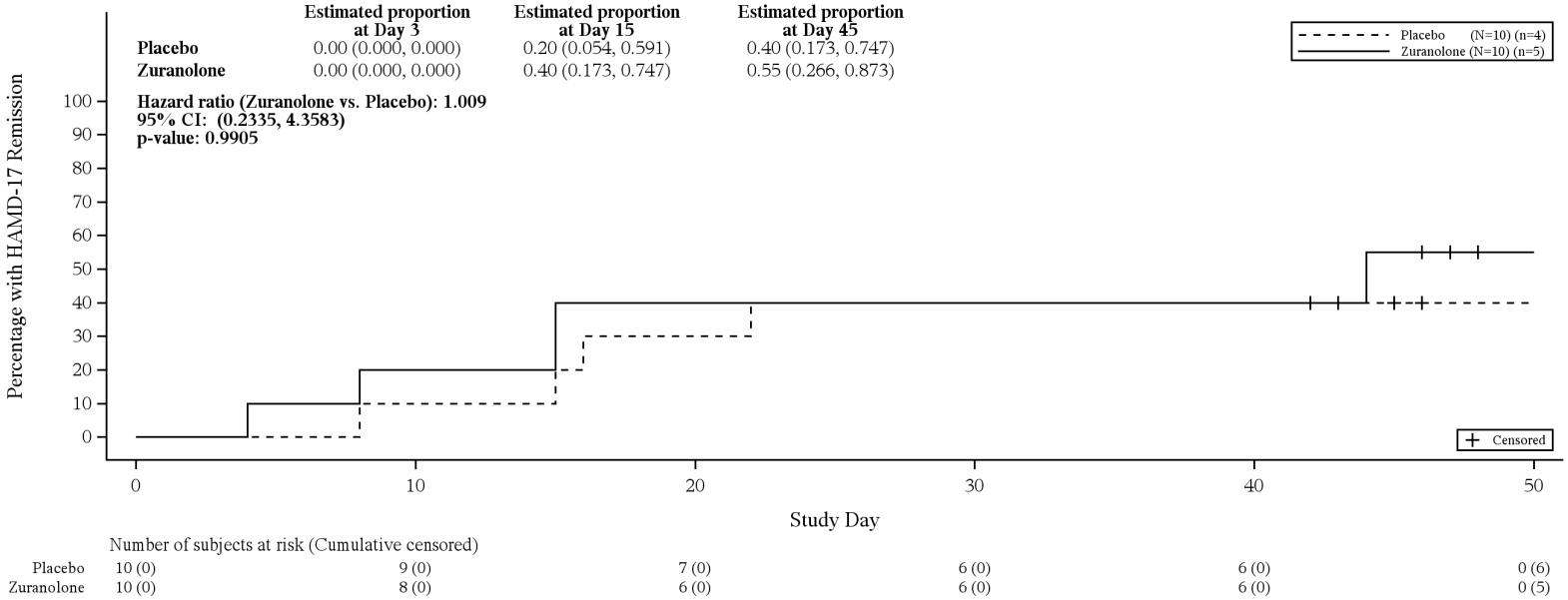
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

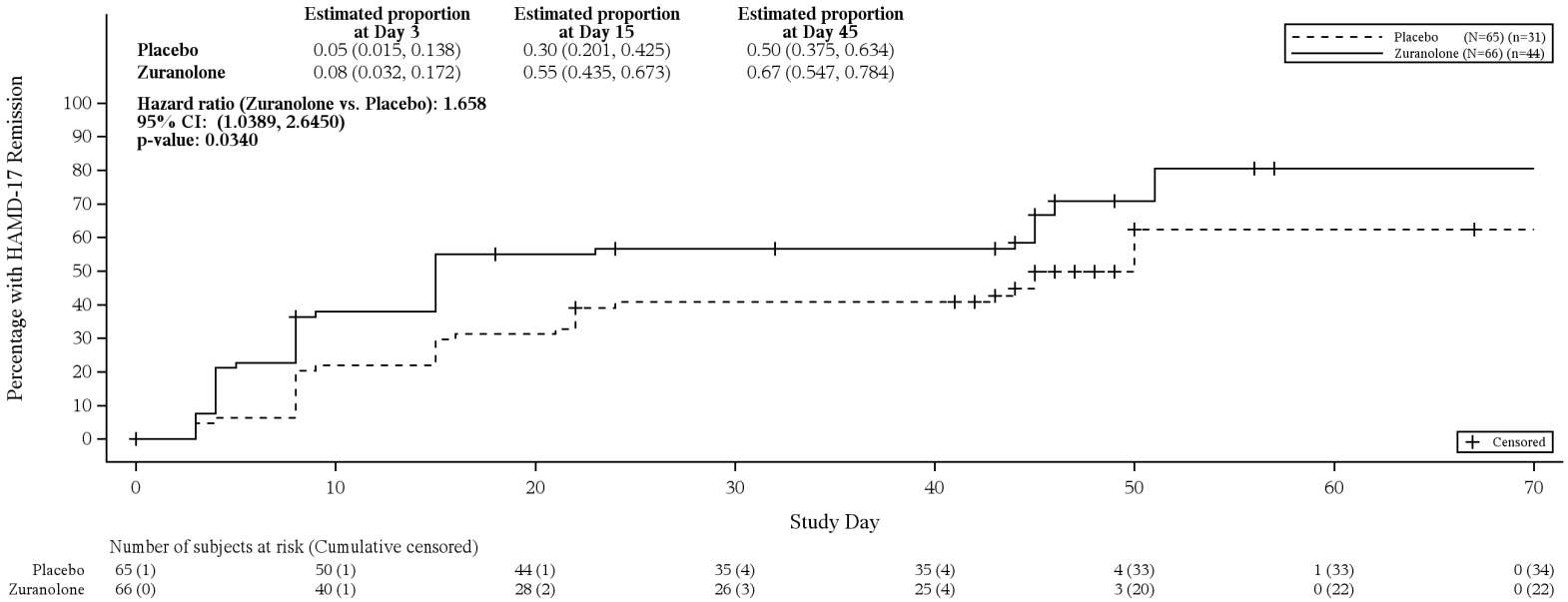
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

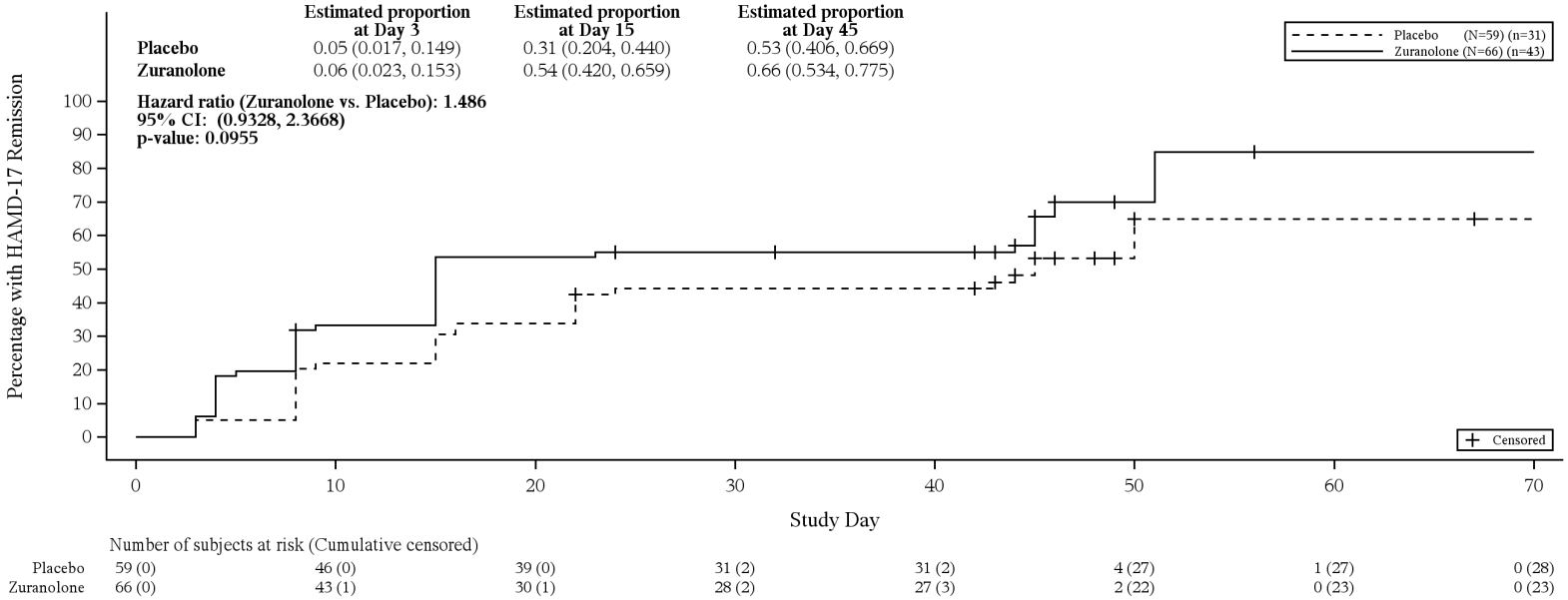
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

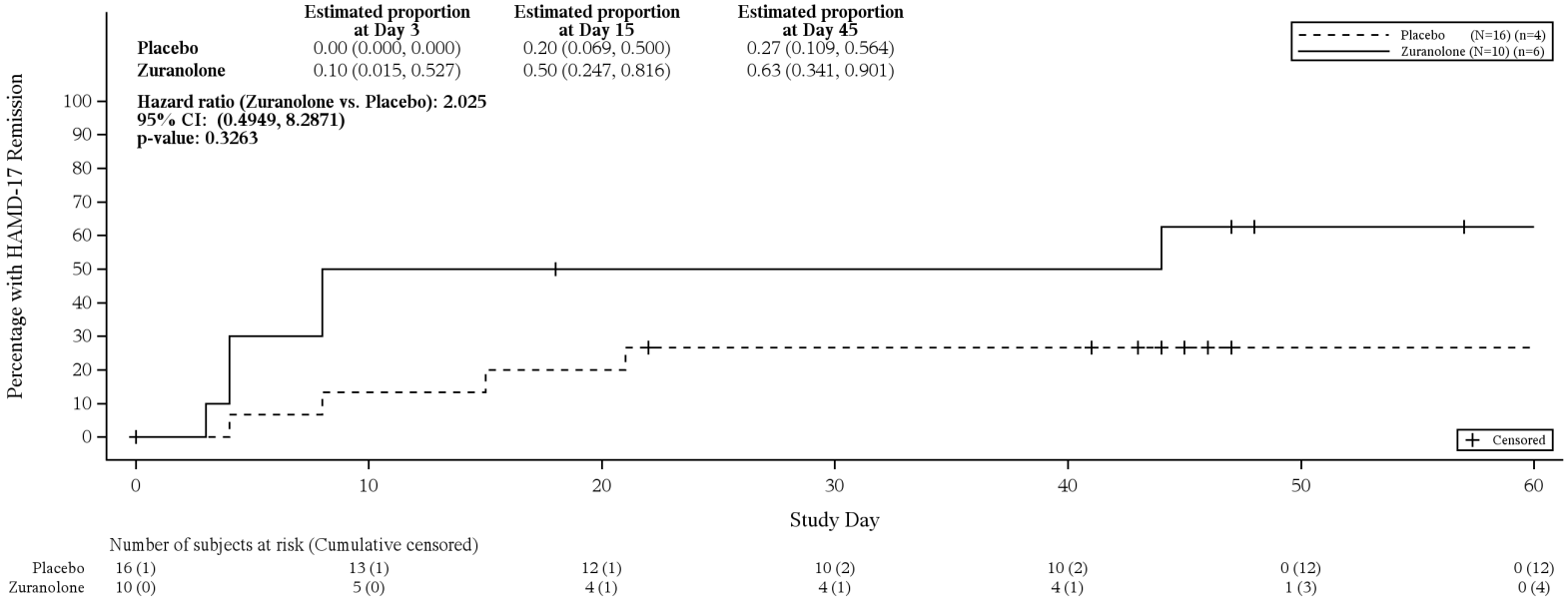
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 17 of 17

History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing HAMD-17 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAMD-17 remission is defined as HAMD-17 total score <=7. Days are calculated from the date of the first dose. Subjects who are not responders are censored at the day of the last available evaluation.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-201-by.sas:f-hamd-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

4.2 MADRS

4.2.1 MMRM

Model-based Results on Change from Baseline in Montgomery-Asberg Depression Rating Scale (MADRS) Total Score: 217-PPD-201B - ITT population

Page: 1 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 3		
n	74	74
LS Mean (SE)	-11.58 (1.217)	-14.63 (1.211)
95% CI for the LS Mean	-13.99, -9.18	-17.03, -12.24
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.05 (1.725)
95% CI for the LS Mean		-6.46, 0.36
p-value		0.0791
Hedges' g (Zuranolone vs. Placebo)		-0.289
95% CI for Hedges' g		-0.6131, 0.0347
Day 8		
n	74	75
LS Mean (SE)	-16.15 (1.318)	-20.18 (1.306)
95% CI for the LS Mean	-18.76, -13.55	-22.76, -17.60
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.03 (1.863)
95% CI for the LS Mean		-7.71, -0.35
p-value		0.0322
Hedges' g (Zuranolone vs. Placebo)		-0.353
95% CI for Hedges' g		-0.6762, -0.0289

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The MADRS total score was calculated as the sum of the 10 individual item scores. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-madrs-mmrm-201-ovr.sas:t-madrs-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Montgomery-Asberg Depression Rating Scale (MADRS) Total Score: 217-PPD-201B - ITT population

Page: 2 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	-17.44 (1.350)	-22.01 (1.338)
95% CI for the LS Mean	-20.11, -14.77	-24.65, -19.36
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.57 (1.909)
95% CI for the LS Mean		-8.34, -0.79
p-value		0.0180
Hedges' g (Zuranolone vs. Placebo)		-0.393
95% CI for Hedges' g		-0.7191, -0.0662
Day 21		
n	73	74
LS Mean (SE)	-17.70 (1.360)	-21.99 (1.349)
95% CI for the LS Mean	-20.39, -15.01	-24.66, -19.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.29 (1.923)
95% CI for the LS Mean		-8.09, -0.49
p-value		0.0271
Hedges' g (Zuranolone vs. Placebo)		-0.366
95% CI for Hedges' g		-0.6924, -0.0403

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The MADRS total score was calculated as the sum of the 10 individual item scores. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-madrs-mmrm-201-ovr.sas:t-madrs-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Montgomery-Asberg Depression Rating Scale (MADRS) Total Score: 217-PPD-201B - ITT population

Page: 3 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 45		
n	69	73
LS Mean (SE)	-18.87 (1.296)	-24.66 (1.271)
95% CI for the LS Mean	-21.43, -16.31	-27.17, -22.15
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-5.79 (1.824)
95% CI for the LS Mean		-9.40, -2.19
p-value		0.0018
Hedges' g (Zuranolone vs. Placebo)		-0.530
95% CI for Hedges' g		-0.8651, -0.1955

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The MADRS total score was calculated as the sum of the 10 individual item scores. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-madrs-mmrm-201-ovr.sas:t-madrs-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.2.2 Ansprechen

4.2.2.1 Responder-Analysen

4.2.2.1 .1 ITT-Population

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with a response, n (%) [2]	20 (26.7)	30 (39.5)
Number of subjects with missing evaluation, n (%)	1 (1.3)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.466
95% CI for the RR		(0.919, 2.338)
p-value for RR		0.1083
OR - Odds Ratio (Zuranolone vs. Placebo)		1.790
95% CI for the OR		(0.896, 3.578)
p-value for OR		0.0991
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.127
95% CI for the ARR		(-0.023, 0.277)
p-value for ARR		0.0964

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-ovr.sas:t-madrs-resp50-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

Page: 2 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with a response, n (%) [2]	37 (49.3)	48 (63.2)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.265
95% CI for the RR		(0.949, 1.686)
p-value for RR		0.1093
OR - Odds Ratio (Zuranolone vs. Placebo)		1.754
95% CI for the OR		(0.916, 3.362)
p-value for OR		0.0903
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.137
95% CI for the ARR		(-0.020, 0.294)
p-value for ARR		0.0869

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-ovr.sas:t-madrs-resp50-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

Page: 3 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with a response, n (%) [2]	35 (46.7)	54 (71.1)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.512
95% CI for the RR		(1.142, 2.001)
p-value for RR		0.0038
OR - Odds Ratio (Zuranolone vs. Placebo)		2.795
95% CI for the OR		(1.427, 5.474)
p-value for OR		0.0027
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.243
95% CI for the ARR		(0.091, 0.395)
p-value for ARR		0.0017

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-ovr.sas:t-madrs-resp50-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

Page: 4 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with a response, n (%) [2]	38 (50.7)	52 (68.4)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.345
95% CI for the RR		(1.026, 1.764)
p-value for RR		0.0320
OR - Odds Ratio (Zuranolone vs. Placebo)		2.101
95% CI for the OR		(1.083, 4.079)
p-value for OR		0.0282
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.177
95% CI for the ARR		(0.022, 0.331)
p-value for ARR		0.0248

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-ovr.sas:t-madrs-resp50-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

Page: 5 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	39 (52.0)	54 (71.1)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.356
95% CI for the RR		(1.044, 1.762)
p-value for RR		0.0226
OR - Odds Ratio (Zuranolone vs. Placebo)		2.257
95% CI for the OR		(1.147, 4.442)
p-value for OR		0.0184
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.189
95% CI for the ARR		(0.036, 0.343)
p-value for ARR		0.0155

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-ovr.sas:t-madrs-resp50-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.2.2.1 .2 Subgruppen

4.2.2.1 .2 .1 Interaktionstest

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	35 (46.7)	54 (71.1)	
Number of subjects with response at Day 45, n (%)	39 (52.0)	54 (71.1)	
Age Group (years)			0.9233
Day 15			
18 - 24, n / N (%)	12/25 (48.0)	12/17 (70.6)	
25 - 45, n / N (%)	23/50 (46.0)	42/59 (71.2)	
Day 45			
18 - 24, n / N (%)	13/25 (52.0)	10/17 (58.8)	
25 - 45, n / N (%)	26/50 (52.0)	44/59 (74.6)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-int.sas:t-madrs-resp50-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.0990
Day 15			
<28, n / N (%)	12/22 (54.5)	20/30 (66.7)	
>=28, n / N (%)	23/53 (43.4)	34/46 (73.9)	
Day 45			
<28, n / N (%)	13/22 (59.1)	19/30 (63.3)	
>=28, n / N (%)	26/53 (49.1)	35/46 (76.1)	
Race Group (Black or African American, White)			0.9924
Day 15			
Black or African American, n / N (%)	13/32 (40.6)	22/31 (71.0)	
White, n / N (%)	20/40 (50.0)	31/44 (70.5)	
Day 45			
Black or African American, n / N (%)	16/32 (50.0)	22/31 (71.0)	
White, n / N (%)	22/40 (55.0)	31/44 (70.5)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-int.sas:t-madrs-resp50-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.5527
Day 15			
Yes, n / N (%)	6/13 (46.2)	12/16 (75.0)	
No, n / N (%)	29/62 (46.8)	42/60 (70.0)	
Day 45			
Yes, n / N (%)	6/13 (46.2)	12/16 (75.0)	
No, n / N (%)	33/62 (53.2)	42/60 (70.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-int.sas:t-madrs-resp50-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.5450(a) 0.1817(b) 0.0223(c)
Day 15			
<=24.9, n / N (%)	7/21 (33.3)	9/13 (69.2)	
25-29.9, n / N (%)	8/20 (40.0)	16/21 (76.2)	
>=30, n / N (%)	20/34 (58.8)	29/42 (69.0)	
Day 45			
<=24.9, n / N (%)	9/21 (42.9)	11/13 (84.6)	
25-29.9, n / N (%)	11/20 (55.0)	17/21 (81.0)	
>=30, n / N (%)	19/34 (55.9)	26/42 (61.9)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-int.sas:t-madrs-resp50-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.4075
Day 15			
3rd Trimester, n / N (%)	13/32 (40.6)	22/32 (68.8)	
Postpartum, n / N (%)	22/43 (51.2)	32/44 (72.7)	
Day 45			
3rd Trimester, n / N (%)	18/32 (56.3)	24/32 (75.0)	
Postpartum, n / N (%)	21/43 (48.8)	30/44 (68.2)	
Family History of PPD			0.8751
Day 15			
Yes, n / N (%)	4/10 (40.0)	8/10 (80.0)	
No/Unknown, n / N (%)	31/65 (47.7)	46/66 (69.7)	
Day 45			
Yes, n / N (%)	7/10 (70.0)	6/10 (60.0)	
No/Unknown, n / N (%)	32/65 (49.2)	48/66 (72.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-int.sas:t-madrs-resp50-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.2347
Day 15			
1st Episode, n / N (%)	30/59 (50.8)	47/66 (71.2)	
Recurrent Episode, n / N (%)	5/16 (31.3)	7/10 (70.0)	
Day 45			
1st Episode, n / N (%)	33/59 (55.9)	48/66 (72.7)	
Recurrent Episode, n / N (%)	6/16 (37.5)	6/10 (60.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	5/8 (62.5)	9/10 (90.0)	
>=20, n / N (%)	30/67 (44.8)	45/66 (68.2)	
Day 45			
<20, n / N (%)	6/8 (75.0)	7/10 (70.0)	
>=20, n / N (%)	33/67 (49.3)	47/66 (71.2)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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4.2.2.1 .2 .2 Subgruppenanalysen

4.2.2.1 .2 .2 .1 Alter

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

Page: 1 of 6

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 3		
Number of subjects with a response, n (%) [2]	8 (32.0)	8 (47.1)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.494
95% CI for the RR		(0.717, 3.110)
p-value for RR		0.2836
Day 8		
Number of subjects with a response, n (%) [2]	12 (48.0)	12 (70.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.494
95% CI for the RR		(0.920, 2.426)
p-value for RR		0.1049

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

Page: 2 of 6

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 15		
Number of subjects with a response, n (%) [2]	12 (48.0)	12 (70.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.494
95% CI for the RR		(0.900, 2.480)
p-value for RR		0.1209
Day 21		
Number of subjects with a response, n (%) [2]	12 (48.0)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.369
95% CI for the RR		(0.824, 2.275)
p-value for RR		0.2252

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 45		
Number of subjects with a response, n (%) [2]	13 (52.0)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.149
95% CI for the RR		(0.669, 1.972)
p-value for RR		0.6144

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 3		
Number of subjects with a response, n (%) [2]	12 (24.0)	22 (37.3)
Number of subjects with missing evaluation, n (%)	1 (2.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.498
95% CI for the RR		(0.829, 2.708)
p-value for RR		0.1811
Day 8		
Number of subjects with a response, n (%) [2]	25 (50.0)	36 (61.0)
Number of subjects with missing evaluation, n (%)	1 (2.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.177
95% CI for the RR		(0.836, 1.655)
p-value for RR		0.3505

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 15		
Number of subjects with a response, n (%) [2]	23 (46.0)	42 (71.2)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.492
95% CI for the RR		(1.065, 2.090)
p-value for RR		0.0200
Day 21		
Number of subjects with a response, n (%) [2]	26 (52.0)	41 (69.5)
Number of subjects with missing evaluation, n (%)	2 (4.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.288
95% CI for the RR		(0.939, 1.768)
p-value for RR		0.1164

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 45		
Number of subjects with a response, n (%) [2]	26 (52.0)	44 (74.6)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.383
95% CI for the RR		(1.020, 1.875)
p-value for RR		0.0370

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.2.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 3		
Number of subjects with a response, n (%) [2]	6 (27.3)	9 (30.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.105
95% CI for the RR		(0.460, 2.654)
p-value for RR		0.8225
Day 8		
Number of subjects with a response, n (%) [2]	13 (59.1)	15 (50.0)
Number of subjects with missing evaluation, n (%)	0	1 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.850
95% CI for the RR		(0.519, 1.392)
p-value for RR		0.5193

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 15		
Number of subjects with a response, n (%) [2]	12 (54.5)	20 (66.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.228
95% CI for the RR		(0.776, 1.945)
p-value for RR		0.3806
Day 21		
Number of subjects with a response, n (%) [2]	12 (54.5)	17 (56.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.044
95% CI for the RR		(0.644, 1.694)
p-value for RR		0.8614

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 45		
Number of subjects with a response, n (%) [2]	13 (59.1)	19 (63.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.077
95% CI for the RR		(0.692, 1.676)
p-value for RR		0.7419

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 3		
Number of subjects with a response, n (%) [2]	14 (26.4)	21 (45.7)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.703
95% CI for the RR		(0.983, 2.953)
p-value for RR		0.0578
Day 8		
Number of subjects with a response, n (%) [2]	24 (45.3)	33 (71.7)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.561
95% CI for the RR		(1.103, 2.210)
p-value for RR		0.0119

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 15		
Number of subjects with a response, n (%) [2]	23 (43.4)	34 (73.9)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.679
95% CI for the RR		(1.179, 2.391)
p-value for RR		0.0041
Day 21		
Number of subjects with a response, n (%) [2]	26 (49.1)	35 (76.1)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.529
95% CI for the RR		(1.108, 2.109)
p-value for RR		0.0097

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 45		
Number of subjects with a response, n (%) [2]	26 (49.1)	35 (76.1)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.529
95% CI for the RR		(1.109, 2.108)
p-value for RR		0.0096

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.2.2.1 .2 .2 .3 Abstammung

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 3		
Number of subjects with a response, n (%) [2]	7 (21.9)	11 (35.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.685
95% CI for the RR		(0.764, 3.719)
p-value for RR		0.1963
Day 8		
Number of subjects with a response, n (%) [2]	15 (46.9)	17 (54.8)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.215
95% CI for the RR		(0.750, 1.969)
p-value for RR		0.4281

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

Page: 2 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 15		
Number of subjects with a response, n (%) [2]	13 (40.6)	22 (71.0)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.815
95% CI for the RR		(1.147, 2.872)
p-value for RR		0.0110
Day 21		
Number of subjects with a response, n (%) [2]	18 (56.3)	18 (58.1)
Number of subjects with missing evaluation, n (%)	1 (3.1)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.072
95% CI for the RR		(0.703, 1.636)
p-value for RR		0.7456

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 45		
Number of subjects with a response, n (%) [2]	16 (50.0)	22 (71.0)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.475
95% CI for the RR		(0.986, 2.206)
p-value for RR		0.0587

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 3		
Number of subjects with a response, n (%) [2]	13 (32.5)	18 (40.9)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.239
95% CI for the RR		(0.702, 2.186)
p-value for RR		0.4601
Day 8		
Number of subjects with a response, n (%) [2]	21 (52.5)	30 (68.2)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.278
95% CI for the RR		(0.894, 1.827)
p-value for RR		0.1784

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	20 (50.0)	31 (70.5)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.387
95% CI for the RR		(0.969, 1.984)
p-value for RR		0.0739
Day 21		
Number of subjects with a response, n (%) [2]	19 (47.5)	34 (77.3)
Number of subjects with missing evaluation, n (%)	1 (2.5)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.601
95% CI for the RR		(1.115, 2.298)
p-value for RR		0.0107

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	22 (55.0)	31 (70.5)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.261
95% CI for the RR		(0.898, 1.769)
p-value for RR		0.1805

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.2.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 3		
Number of subjects with a response, n (%) [2]	4 (30.8)	6 (37.5)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.198
95% CI for the RR		(0.430, 3.339)
p-value for RR		0.7301
Day 8		
Number of subjects with a response, n (%) [2]	5 (38.5)	11 (68.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.745
95% CI for the RR		(0.814, 3.739)
p-value for RR		0.1522

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 15		
Number of subjects with a response, n (%) [2]	6 (46.2)	12 (75.0)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.592
95% CI for the RR		(0.831, 3.052)
p-value for RR		0.1612
Day 21		
Number of subjects with a response, n (%) [2]	5 (38.5)	12 (75.0)
Number of subjects with missing evaluation, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.918
95% CI for the RR		(0.908, 4.051)
p-value for RR		0.0876

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 45		
Number of subjects with a response, n (%) [2]	6 (46.2)	12 (75.0)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.608
95% CI for the RR		(0.836, 3.092)
p-value for RR		0.1544

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 3		
Number of subjects with a response, n (%) [2]	16 (25.8)	24 (40.0)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.529
95% CI for the RR		(0.907, 2.578)
p-value for RR		0.1110
Day 8		
Number of subjects with a response, n (%) [2]	32 (51.6)	37 (61.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.171
95% CI for the RR		(0.856, 1.601)
p-value for RR		0.3232

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 15		
Number of subjects with a response, n (%) [2]	29 (46.8)	42 (70.0)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.482
95% CI for the RR		(1.085, 2.024)
p-value for RR		0.0134
Day 21		
Number of subjects with a response, n (%) [2]	33 (53.2)	40 (66.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.246
95% CI for the RR		(0.928, 1.674)
p-value for RR		0.1440

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 45		
Number of subjects with a response, n (%) [2]	33 (53.2)	42 (70.0)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.300
95% CI for the RR		(0.975, 1.733)
p-value for RR		0.0739

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.2.2.1 .2 .2 .5 BMI

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 3		
Number of subjects with a response, n (%) [2]	6 (28.6)	5 (38.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.367
95% CI for the RR		(0.523, 3.569)
p-value for RR		0.5235
Day 8		
Number of subjects with a response, n (%) [2]	10 (47.6)	7 (53.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.148
95% CI for the RR		(0.595, 2.215)
p-value for RR		0.6805

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 15		
Number of subjects with a response, n (%) [2]	7 (33.3)	9 (69.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.109
95% CI for the RR		(1.043, 4.262)
p-value for RR		0.0377
Day 21		
Number of subjects with a response, n (%) [2]	8 (38.1)	9 (69.2)
Number of subjects with missing evaluation, n (%)	2 (9.5)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.845
95% CI for the RR		(0.973, 3.499)
p-value for RR		0.0606

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 45		
Number of subjects with a response, n (%) [2]	9 (42.9)	11 (84.6)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.005
95% CI for the RR		(1.180, 3.407)
p-value for RR		0.0102

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 3		
Number of subjects with a response, n (%) [2]	3 (15.0)	11 (52.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		3.345
95% CI for the RR		(1.121, 9.985)
p-value for RR		0.0305
Day 8		
Number of subjects with a response, n (%) [2]	7 (35.0)	14 (66.7)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.825
95% CI for the RR		(0.941, 3.536)
p-value for RR		0.0749

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	8 (40.0)	16 (76.2)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.825
95% CI for the RR		(1.010, 3.296)
p-value for RR		0.0463
Day 21		
Number of subjects with a response, n (%) [2]	8 (40.0)	16 (76.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.825
95% CI for the RR		(1.004, 3.314)
p-value for RR		0.0483

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 45		
Number of subjects with a response, n (%) [2]	11 (55.0)	17 (81.0)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.410
95% CI for the RR		(0.894, 2.224)
p-value for RR		0.1396

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 3		
Number of subjects with a response, n (%) [2]	11 (32.4)	14 (33.3)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.026
95% CI for the RR		(0.537, 1.960)
p-value for RR		0.9388
Day 8		
Number of subjects with a response, n (%) [2]	20 (58.8)	27 (64.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.088
95% CI for the RR		(0.759, 1.559)
p-value for RR		0.6459

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 15		
Number of subjects with a response, n (%) [2]	20 (58.8)	29 (69.0)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.169
95% CI for the RR		(0.826, 1.652)
p-value for RR		0.3781
Day 21		
Number of subjects with a response, n (%) [2]	22 (64.7)	27 (64.3)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.989
95% CI for the RR		(0.706, 1.386)
p-value for RR		0.9490

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 45		
Number of subjects with a response, n (%) [2]	19 (55.9)	26 (61.9)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.103
95% CI for the RR		(0.751, 1.620)
p-value for RR		0.6182

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.2.2.1 .2 .2 .6 Beginn der PPD

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 3		
Number of subjects with a response, n (%) [2]	8 (25.0)	16 (50.0)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.969
95% CI for the RR		(0.991, 3.913)
p-value for RR		0.0531
Day 8		
Number of subjects with a response, n (%) [2]	15 (46.9)	21 (65.6)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.378
95% CI for the RR		(0.888, 2.140)
p-value for RR		0.1527

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 15		
Number of subjects with a response, n (%) [2]	13 (40.6)	22 (68.8)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.666
95% CI for the RR		(1.034, 2.686)
p-value for RR		0.0361
Day 21		
Number of subjects with a response, n (%) [2]	15 (46.9)	22 (68.8)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.444
95% CI for the RR		(0.934, 2.232)
p-value for RR		0.0984

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 45		
Number of subjects with a response, n (%) [2]	18 (56.3)	24 (75.0)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.313
95% CI for the RR		(0.912, 1.889)
p-value for RR		0.1429

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 3		
Number of subjects with a response, n (%) [2]	12 (27.9)	14 (31.8)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.140
95% CI for the RR		(0.596, 2.180)
p-value for RR		0.6916
Day 8		
Number of subjects with a response, n (%) [2]	22 (51.2)	27 (61.4)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.199
95% CI for the RR		(0.824, 1.745)
p-value for RR		0.3423

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	22 (51.2)	32 (72.7)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.421
95% CI for the RR		(1.007, 2.007)
p-value for RR		0.0457
Day 21		
Number of subjects with a response, n (%) [2]	23 (53.5)	30 (68.2)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.275
95% CI for the RR		(0.902, 1.802)
p-value for RR		0.1693

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	21 (48.8)	30 (68.2)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.396
95% CI for the RR		(0.965, 2.019)
p-value for RR		0.0762

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.2.2.1 .2 .2 .7 PPD in der Familie

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 3		
Number of subjects with a response, n (%) [2]	2 (20.0)	2 (20.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.617
95% CI for the RR		(0.066, 5.763)
p-value for RR		0.6717
Day 8		
Number of subjects with a response, n (%) [2]	5 (50.0)	8 (80.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.987
95% CI for the RR		(0.129, 7.523)
p-value for RR		0.9899

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	4 (40.0)	8 (80.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.234
95% CI for the RR		(0.135, 11.288)
p-value for RR		0.8525
Day 21		
Number of subjects with a response, n (%) [2]	4 (40.0)	9 (90.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.388
95% CI for the RR		(0.144, 13.343)
p-value for RR		0.7765

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	7 (70.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.529
95% CI for the RR		(0.060, 4.664)
p-value for RR		0.5662

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 3		
Number of subjects with a response, n (%) [2]	18 (27.7)	28 (42.4)
Number of subjects with missing evaluation, n (%)	1 (1.5)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.521
95% CI for the RR		(0.940, 2.462)
p-value for RR		0.0879
Day 8		
Number of subjects with a response, n (%) [2]	32 (49.2)	40 (60.6)
Number of subjects with missing evaluation, n (%)	1 (1.5)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.222
95% CI for the RR		(0.893, 1.672)
p-value for RR		0.2095

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	31 (47.7)	46 (69.7)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.451
95% CI for the RR		(1.076, 1.956)
p-value for RR		0.0146
Day 21		
Number of subjects with a response, n (%) [2]	34 (52.3)	43 (65.2)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.237
95% CI for the RR		(0.924, 1.655)
p-value for RR		0.1531

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	32 (49.2)	48 (72.7)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.467
95% CI for the RR		(1.099, 1.957)
p-value for RR		0.0093

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.2.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 3		
Number of subjects with a response, n (%) [2]	18 (30.5)	25 (37.9)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.239
95% CI for the RR		(0.757, 2.027)
p-value for RR		0.3941
Day 8		
Number of subjects with a response, n (%) [2]	31 (52.5)	42 (63.6)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.208
95% CI for the RR		(0.894, 1.634)
p-value for RR		0.2187

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	30 (50.8)	47 (71.2)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.397
95% CI for the RR		(1.043, 1.873)
p-value for RR		0.0251
Day 21		
Number of subjects with a response, n (%) [2]	31 (52.5)	45 (68.2)
Number of subjects with missing evaluation, n (%)	1 (1.7)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.295
95% CI for the RR		(0.966, 1.735)
p-value for RR		0.0834

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	33 (55.9)	48 (72.7)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.297
95% CI for the RR		(0.990, 1.700)
p-value for RR		0.0587

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 3		
Number of subjects with a response, n (%) [2]	2 (12.5)	5 (50.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.423
95% CI for the RR		(0.712, 16.453)
p-value for RR		0.1245
Day 8		
Number of subjects with a response, n (%) [2]	6 (37.5)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.369
95% CI for the RR		(0.474, 3.954)
p-value for RR		0.5615

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	5 (31.3)	7 (70.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.917
95% CI for the RR		(0.620, 5.922)
p-value for RR		0.2583
Day 21		
Number of subjects with a response, n (%) [2]	7 (43.8)	7 (70.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.369
95% CI for the RR		(0.536, 3.495)
p-value for RR		0.5111

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	6 (37.5)	6 (60.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.369
95% CI for the RR		(0.470, 3.985)
p-value for RR		0.5644

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response (50% or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

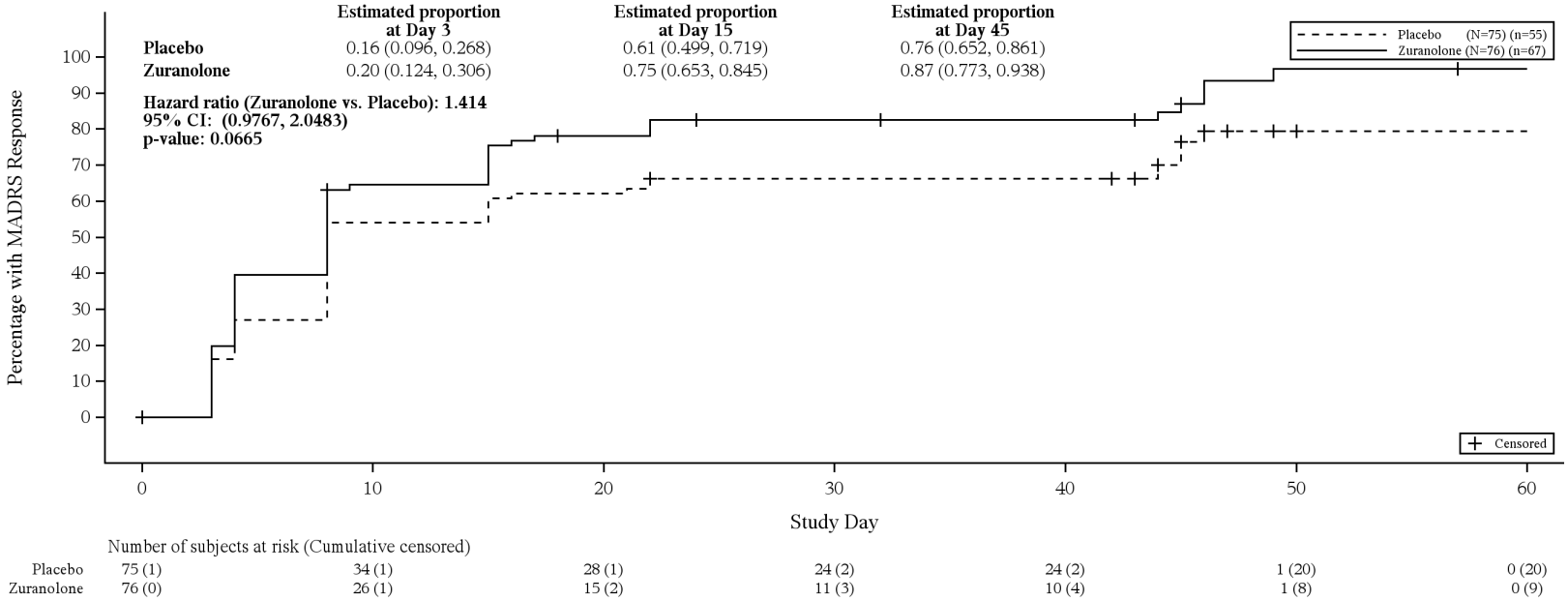
Source: biib125/v_a/germany_amnog/t-madrs-resp50-201-by.sas:t-madrs-resp50-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.2.2.2 TTE-Analysen

4.2.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-ovr.sas:f-madrs-resp50-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	55 (73.3)	67 (88.2)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 16.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	45.0 (22.0, NE)	15.0 (9.0 , 44.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.414
95% CI for the HR		(0.9767 , 2.0483)
p-value for the HR		0.0665

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-ovr.sas:t-madrs-resp50-tte-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.2.2.2 .2 Subgruppen

4.2.2.2 .2 .1 Interaktionstest

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	55 (73.3)	67 (88.2)	
Age Group (years)			
18 - 24, n / N (%)	19/25 (76.0)	15/17 (88.2)	0.5311
25 - 45, n / N (%)	36/50 (72.0)	52/59 (88.1)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	18/22 (81.8)	24/30 (80.0)	0.1030
>=28, n / N (%)	37/53 (69.8)	43/46 (93.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	22/32 (68.8)	26/31 (83.9)	0.8940
White, n / N (%)	31/40 (77.5)	40/44 (90.9)	
Antidepressant Use at Baseline			
Yes, n / N (%)	9/13 (69.2)	15/16 (93.8)	0.4463
No, n / N (%)	46/62 (74.2)	52/60 (86.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-int.sas:t-madrs-resp50-tte-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	15/21 (71.4)	12/13 (92.3)	0.5321(a)
25-29.9, n / N (%)	14/20 (70.0)	19/21 (90.5)	0.5165(b)
>=30, n / N (%)	26/34 (76.5)	36/42 (85.7)	0.1542(c)
Onset of PPD			
3rd Trimester, n / N (%)	24/32 (75.0)	28/32 (87.5)	0.7349
Postpartum, n / N (%)	31/43 (72.1)	39/44 (88.6)	
Family History of PPD			
Yes, n / N (%)	8/10 (80.0)	10/10 (100.0)	0.8622
No/Unknown, n / N (%)	47/65 (72.3)	57/66 (86.4)	
History of PPD			
1st Episode, n / N (%)	47/59 (79.7)	59/66 (89.4)	0.3887
Recurrent Episode, n / N (%)	8/16 (50.0)	8/10 (80.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	7/8 (87.5)	9/10 (90.0)	NA
>=20, n / N (%)	48/67 (71.6)	58/66 (87.9)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-int.sas:t-madrs-resp50-tte-201-int-itta.rtf **Run Date:** 29JUL2025

4.2.2.2 .2 .2 Subgruppenanalysen

4.2.2.2 .2 .2 .1 Alter

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	19 (76.0)	15 (88.2)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (4.0 , 44.0)	8.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.849
95% CI for the HR		(0.9062 , 3.7722)
p-value for the HR		0.0911

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	36 (72.0)	52 (88.1)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 21.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	45.0 (21.0, NE)	17.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.225
95% CI for the HR		(0.7803 , 1.9229)
p-value for the HR		0.3779

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.2.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	18 (81.8)	24 (80.0)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (4.0 , 15.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	15.0 (8.0, NE)	44.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.942
95% CI for the HR		(0.5103 , 1.7397)
p-value for the HR		0.8491

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	37 (69.8)	43 (93.5)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0 , 44.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	46.0 (44.0, NE)	15.0 (8.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.783
95% CI for the HR		(1.1134 , 2.8562)
p-value for the HR		0.0161

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.2.2.2 .2 .2 .3 Abstammung

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	22 (68.8)	26 (83.9)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 22.0)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	22.0 (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.443
95% CI for the HR		(0.7848 , 2.6543)
p-value for the HR		0.2378

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	31 (77.5)	40 (90.9)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 22.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	45.0 (8.0, NE)	15.0 (8.0 , 44.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.426
95% CI for the HR		(0.8744 , 2.3250)
p-value for the HR		0.1550

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.2.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	9 (69.2)	15 (93.8)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 22.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	22.0 (3.0, NE)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (8.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.915
95% CI for the HR		(0.7844 , 4.6733)
p-value for the HR		0.1537

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	46 (74.2)	52 (86.7)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	16.5 (9.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.319
95% CI for the HR		(0.8746 , 1.9888)
p-value for the HR		0.1866

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.2.2.2 .2 .2 .5 BMI

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	15 (71.4)	12 (92.3)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (4.0 , 44.0)	8.0 (4.0 , 17.0)
75th percentile - Q3 (95% CI)	44.0 (8.0, NE)	17.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.815
95% CI for the HR		(0.8132 , 4.0504)
p-value for the HR		0.1456

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	14 (70.0)	19 (90.5)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 15.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.5 (8.0 , 46.0)	4.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	46.0 (16.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.977
95% CI for the HR		(0.9431 , 4.1453)
p-value for the HR		0.0711

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	26 (76.5)	36 (85.7)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (4.0 , 15.0)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	22.0 (8.0, NE)	15.0 (8.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.127
95% CI for the HR		(0.6743 , 1.8847)
p-value for the HR		0.6477

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.2.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	24 (75.0)	28 (87.5)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 44.0)	6.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (16.0, NE)	15.0 (8.0 , 49.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.563
95% CI for the HR		(0.8742 , 2.7933)
p-value for the HR		0.1320

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	31 (72.1)	39 (88.6)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (4.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	16.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.318
95% CI for the HR		(0.8078 , 2.1518)
p-value for the HR		0.2687

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.2.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	8 (80.0)	10 (100.0)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (3.0 , 45.0)	8.0 (3.0 , 8.0)
75th percentile - Q3 (95% CI)	45.0 (8.0, NE)	8.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.972
95% CI for the HR		(0.6387 , 6.0860)
p-value for the HR		0.2379

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	47 (72.3)	57 (86.4)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 16.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	46.0 (21.0, NE)	17.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.389
95% CI for the HR		(0.9322 , 2.0700)
p-value for the HR		0.1063

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.2.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	47 (79.7)	59 (89.4)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	45.0 (16.0, NE)	15.0 (8.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.314
95% CI for the HR		(0.8887 , 1.9421)
p-value for the HR		0.1713

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	8 (50.0)	8 (80.0)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 15.0)	3.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0, NE)	6.0 (3.0 , 22.0)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	22.0 (4.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.270
95% CI for the HR		(0.2586 , 6.2338)
p-value for the HR		0.7687

NOTE 1: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

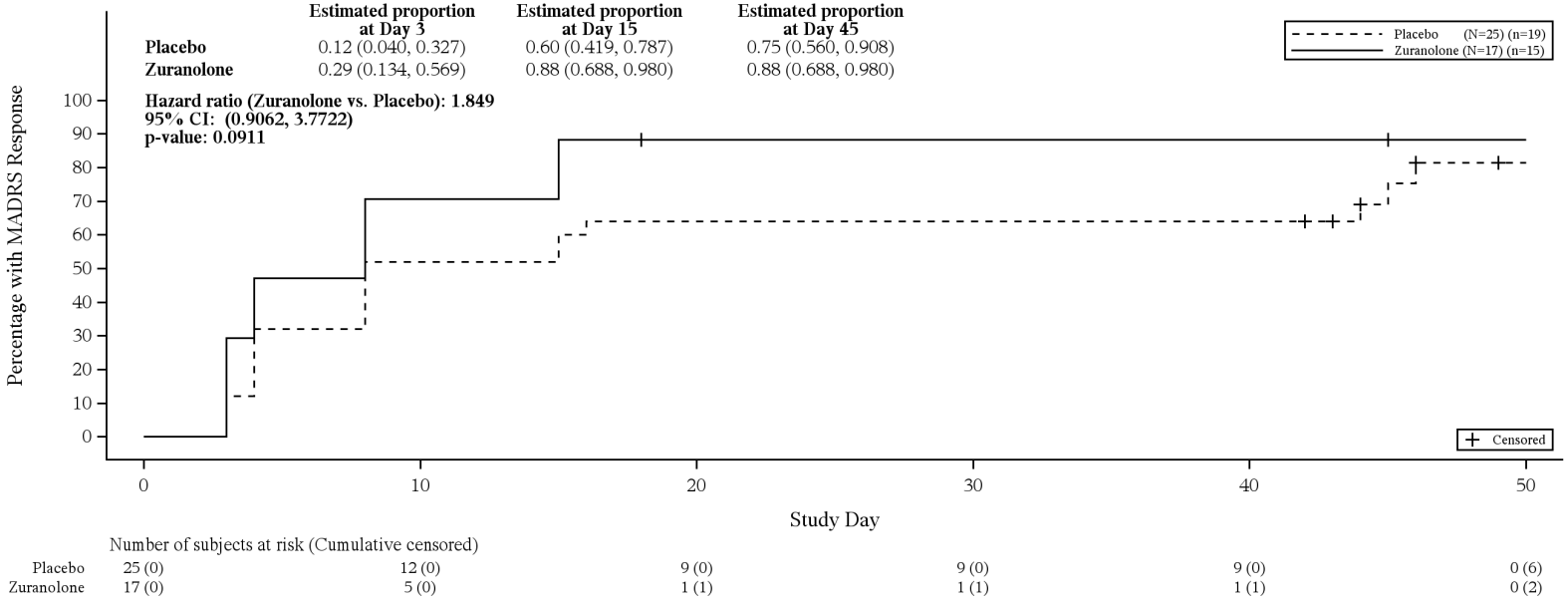
Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-201-by.sas:t-madrs-resp50-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.2.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

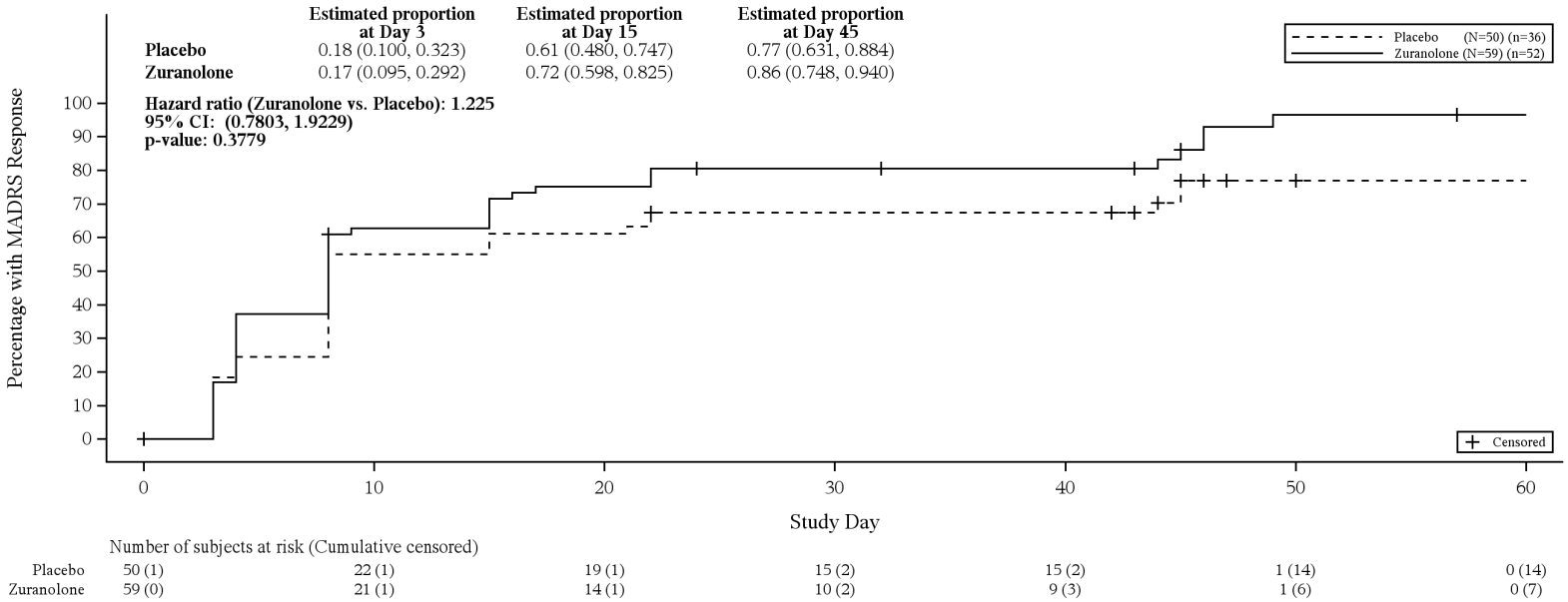
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Number of subjects at risk (Cumulative censored)

Placebo	50 (1)	22 (1)	19 (1)	15 (2)	15 (2)	1 (14)	0 (14)
Zuranolone	59 (0)	21 (1)	14 (1)	10 (2)	9 (3)	1 (6)	0 (7)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

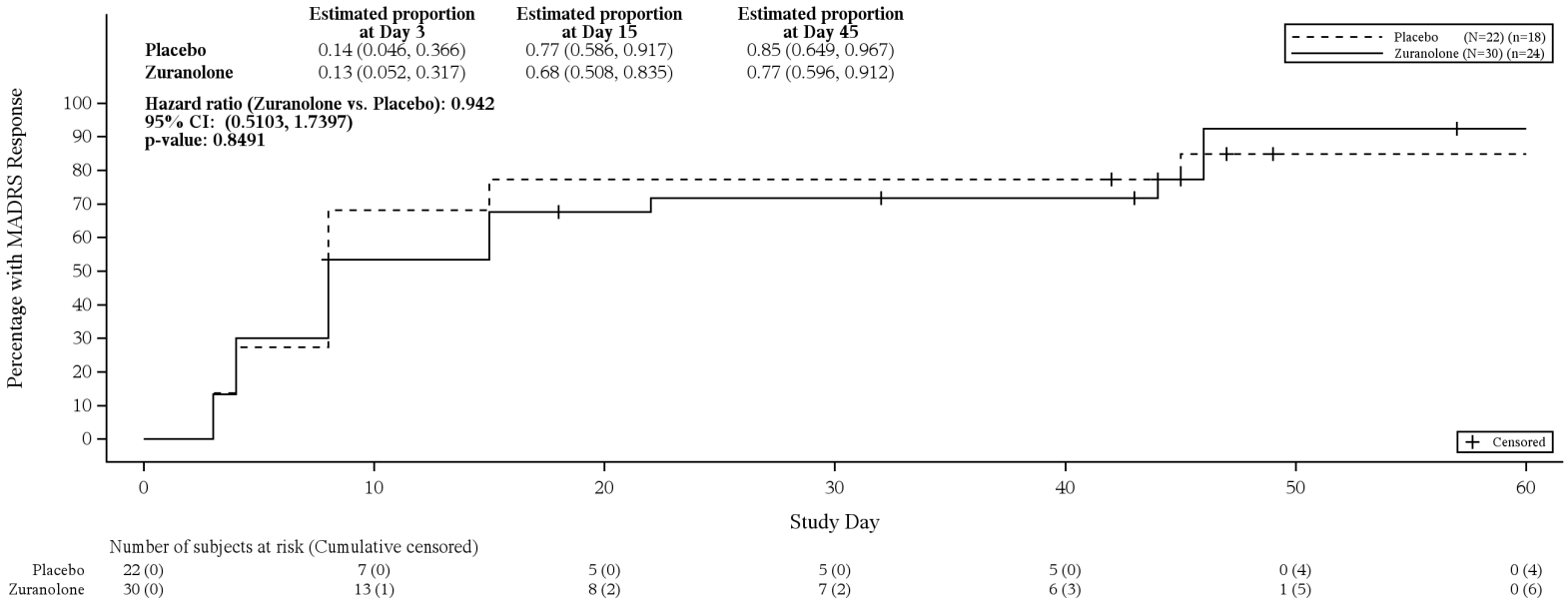
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	7 (0)	5 (0)	5 (0)	5 (0)	0 (4)	0 (4)
Zuranolone	30 (0)	13 (1)	8 (2)	7 (2)	6 (3)	1 (5)	0 (6)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

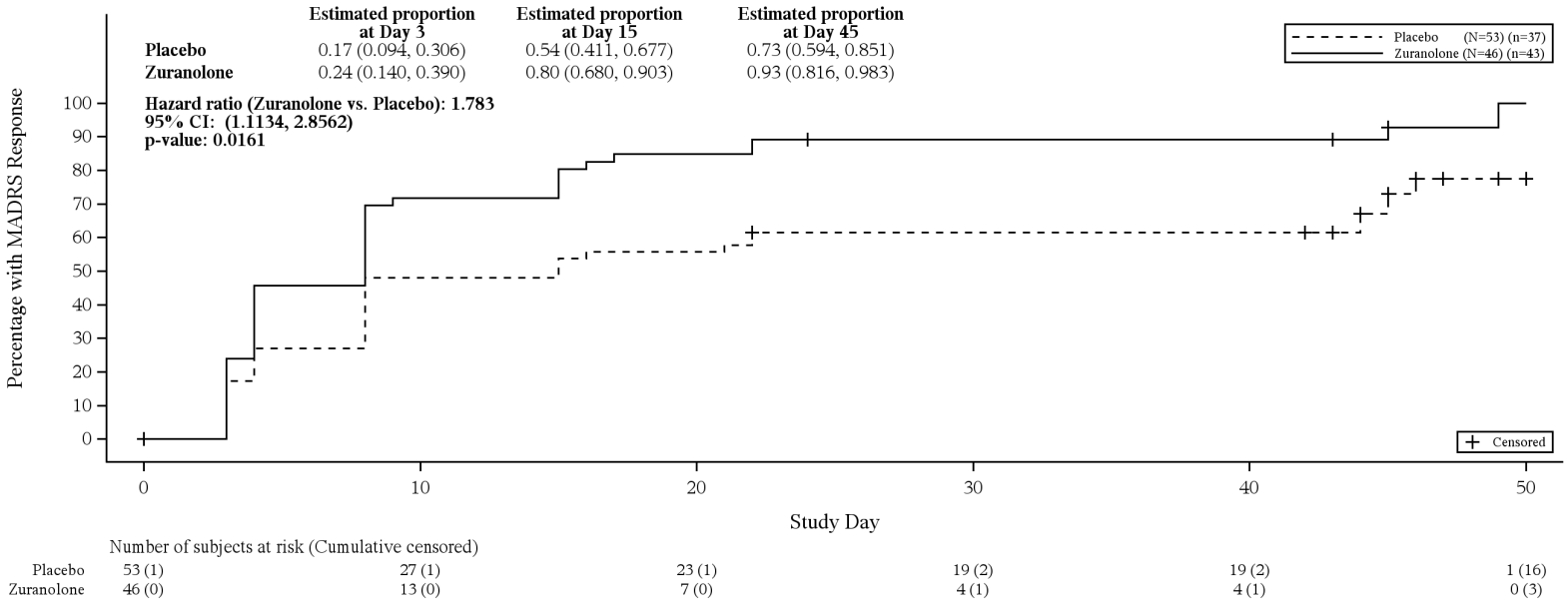
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	53 (1)	27 (1)	23 (1)	19 (2)	19 (2)	1 (16)
Zuranolone	46 (0)	13 (0)	7 (0)	4 (1)	4 (1)	0 (3)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

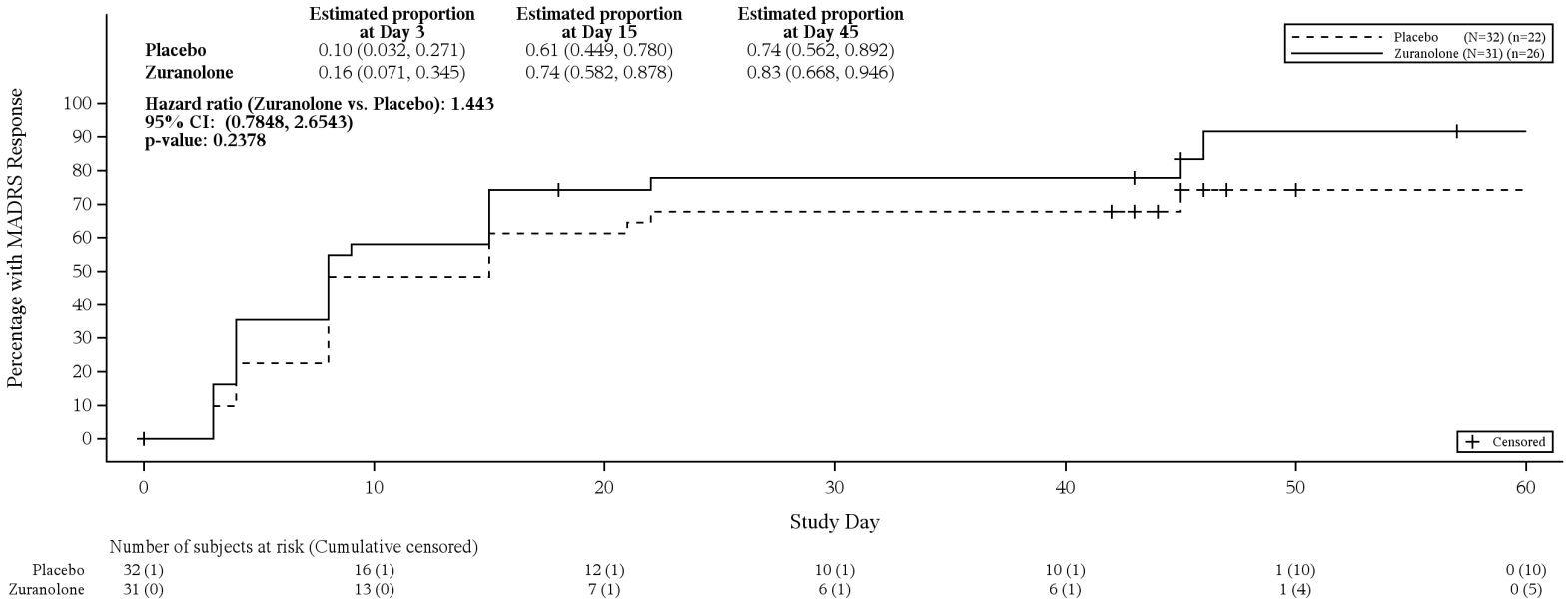
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

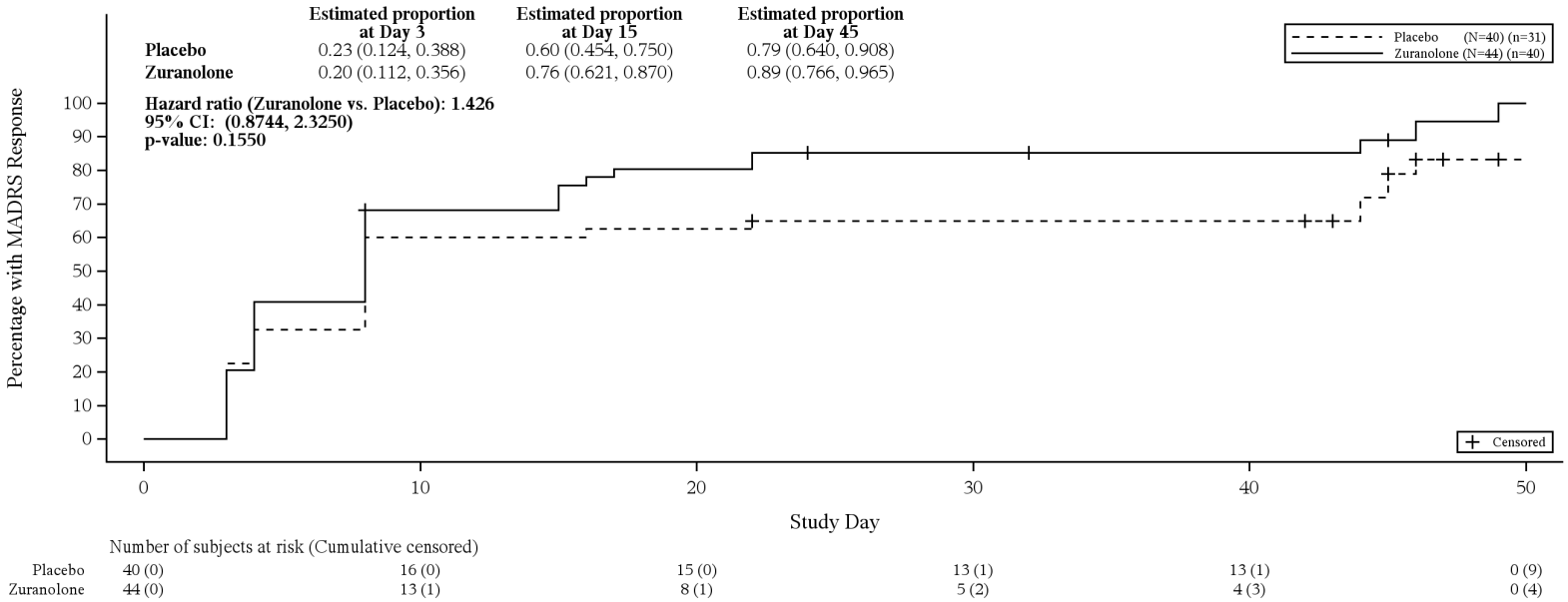
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

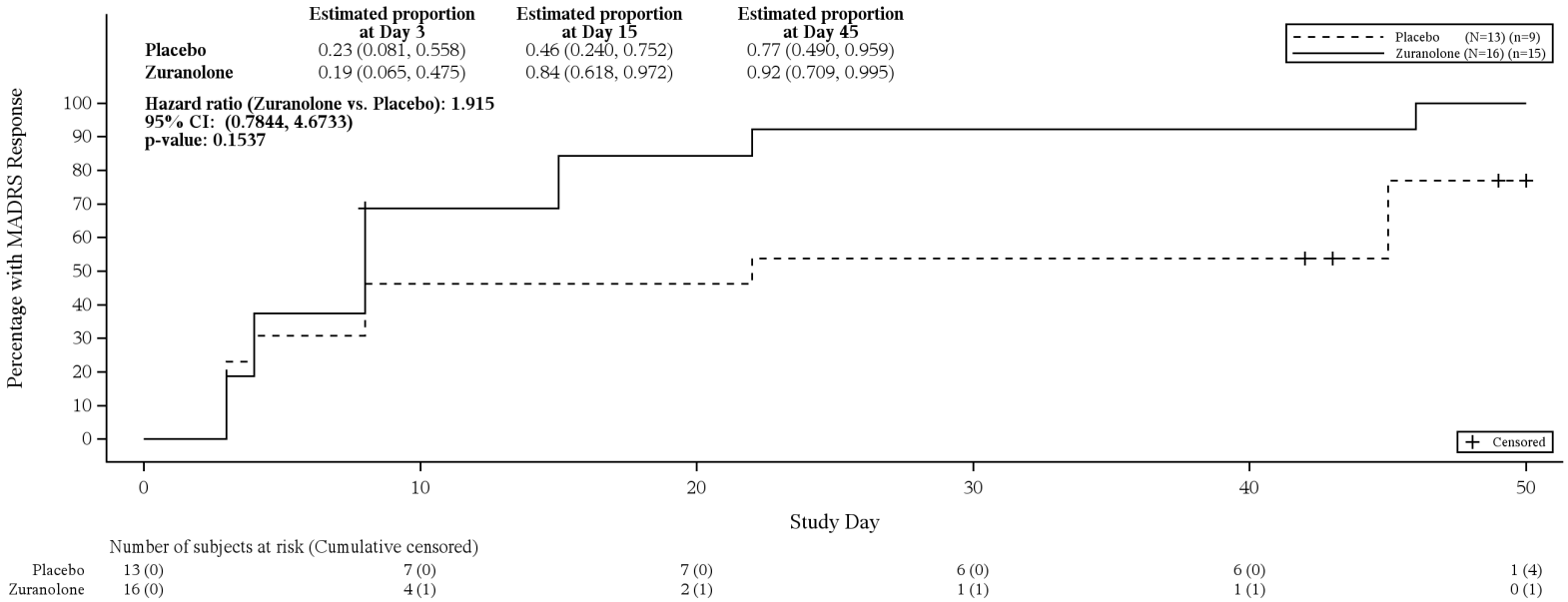
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	13 (0)	7 (0)	7 (0)	6 (0)	6 (0)	1 (4)
Zuranolone	16 (0)	4 (1)	2 (1)	1 (1)	1 (1)	0 (1)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

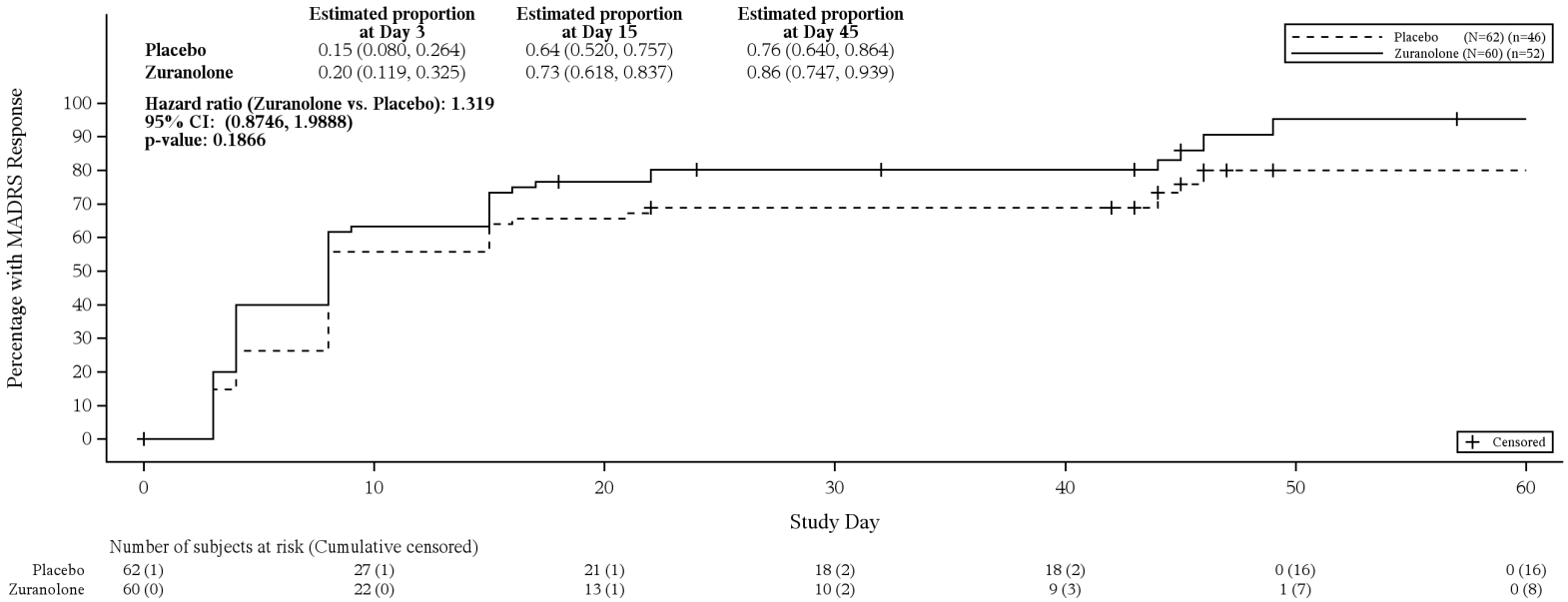
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

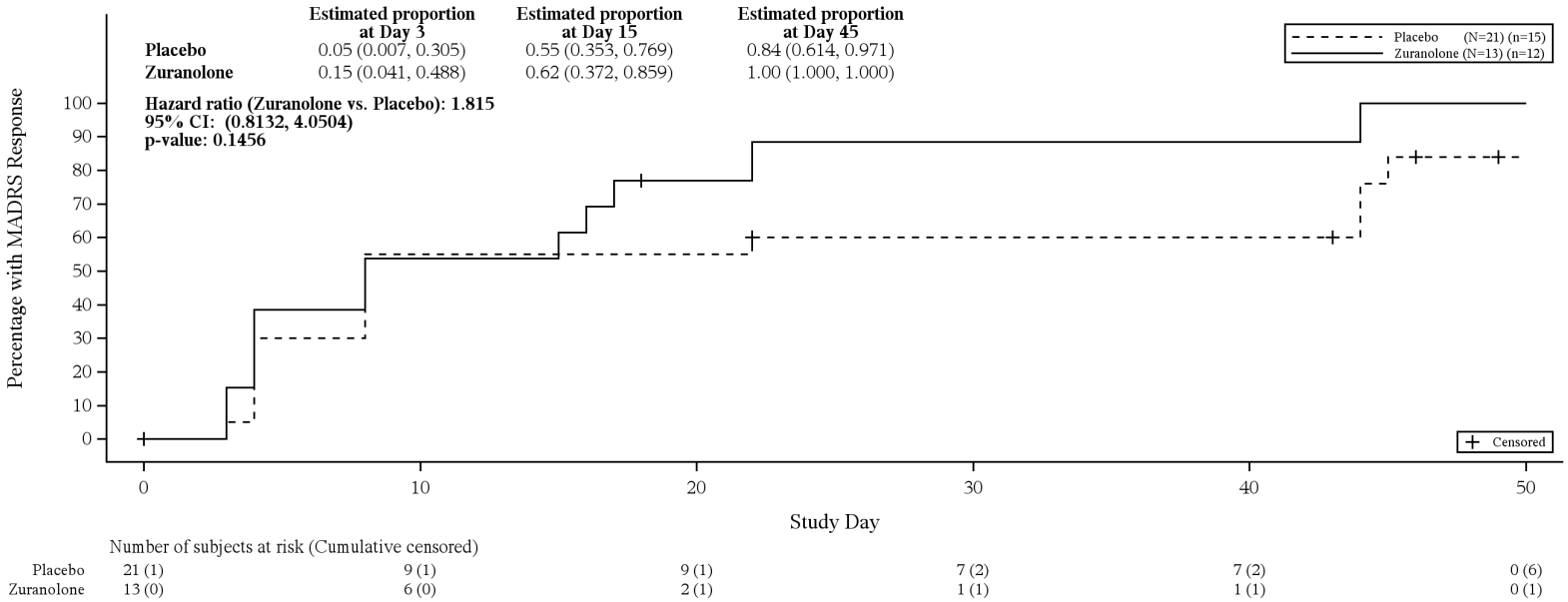
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Number of subjects at risk (Cumulative censored)

Placebo	21 (1)	9 (1)	9 (1)	7 (2)	7 (2)	0 (6)
Zuranolone	13 (0)	6 (0)	2 (1)	1 (1)	1 (1)	0 (1)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

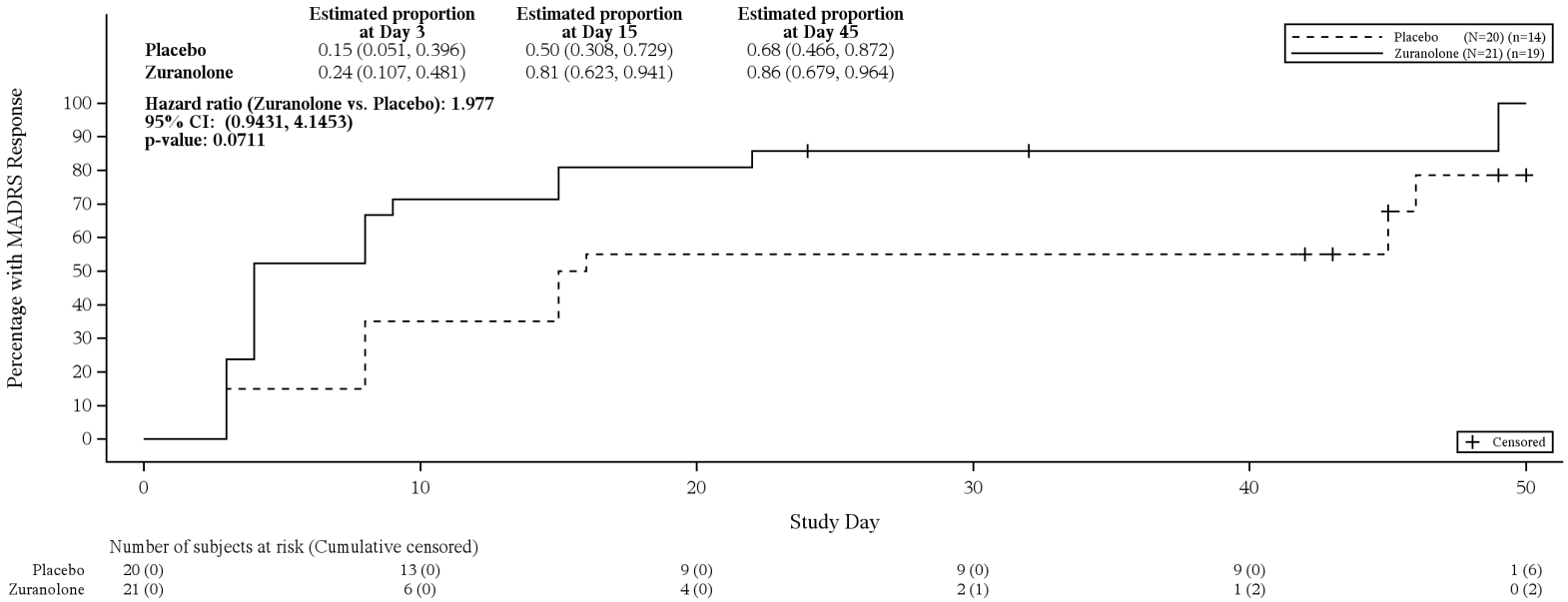
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Number of subjects at risk (Cumulative censored)

Placebo	20 (0)	13 (0)	9 (0)	9 (0)	9 (0)	1 (6)
Zuranolone	21 (0)	6 (0)	4 (0)	2 (1)	1 (2)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

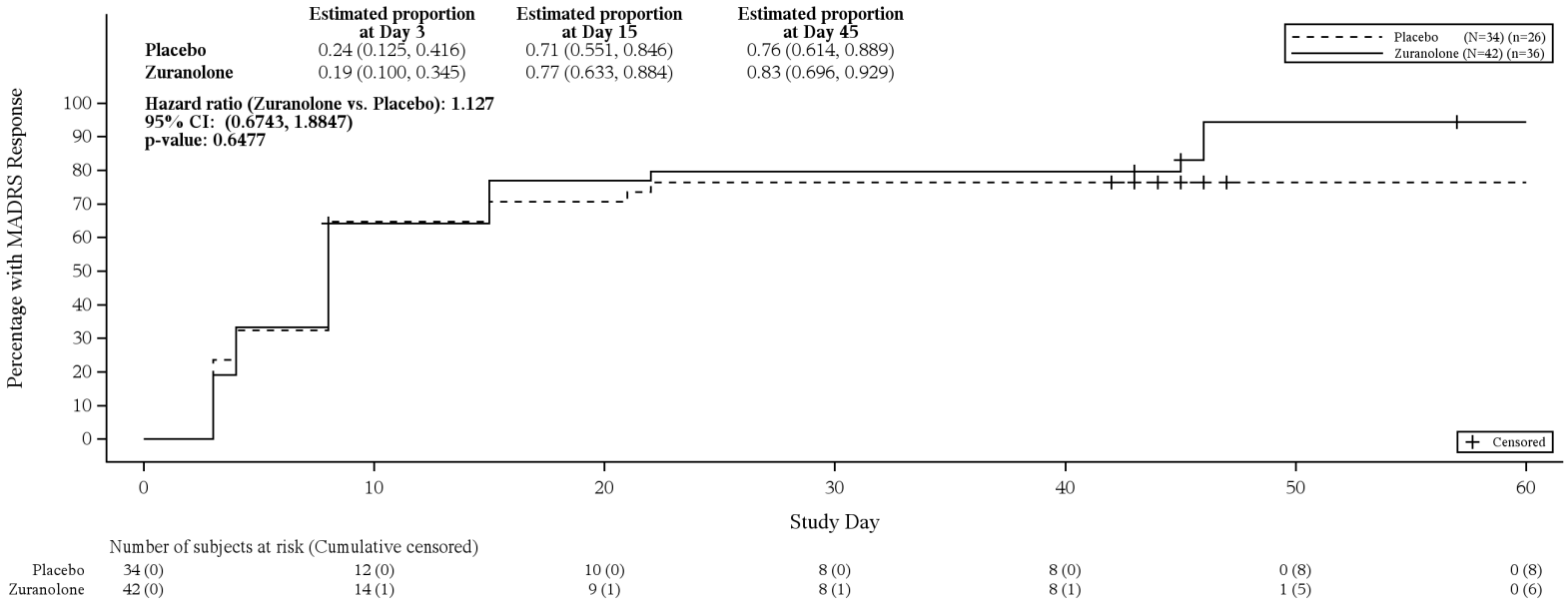
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Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Number of subjects at risk (Cumulative censored)

Placebo	34 (0)	12 (0)	10 (0)	8 (0)	8 (0)	0 (8)	0 (8)
Zuranolone	42 (0)	14 (1)	9 (1)	8 (1)	8 (1)	1 (5)	0 (6)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

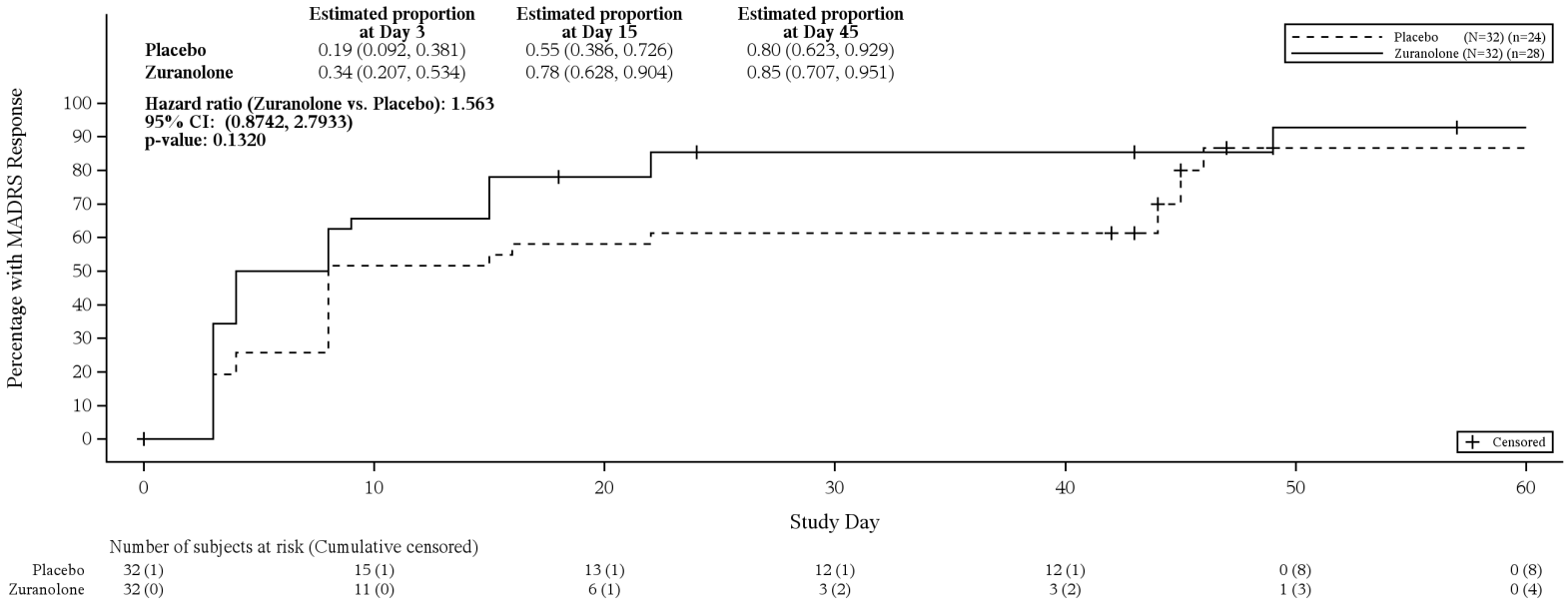
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

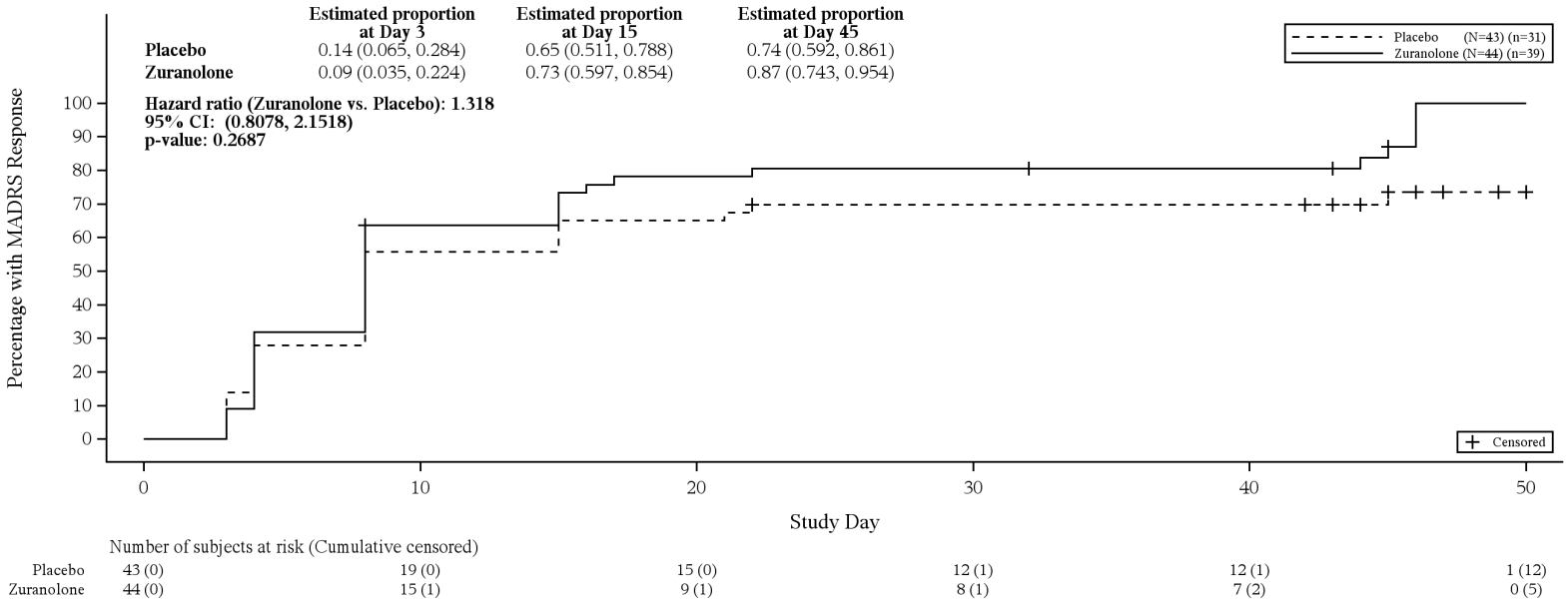
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Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

Page: 13 of 17

Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

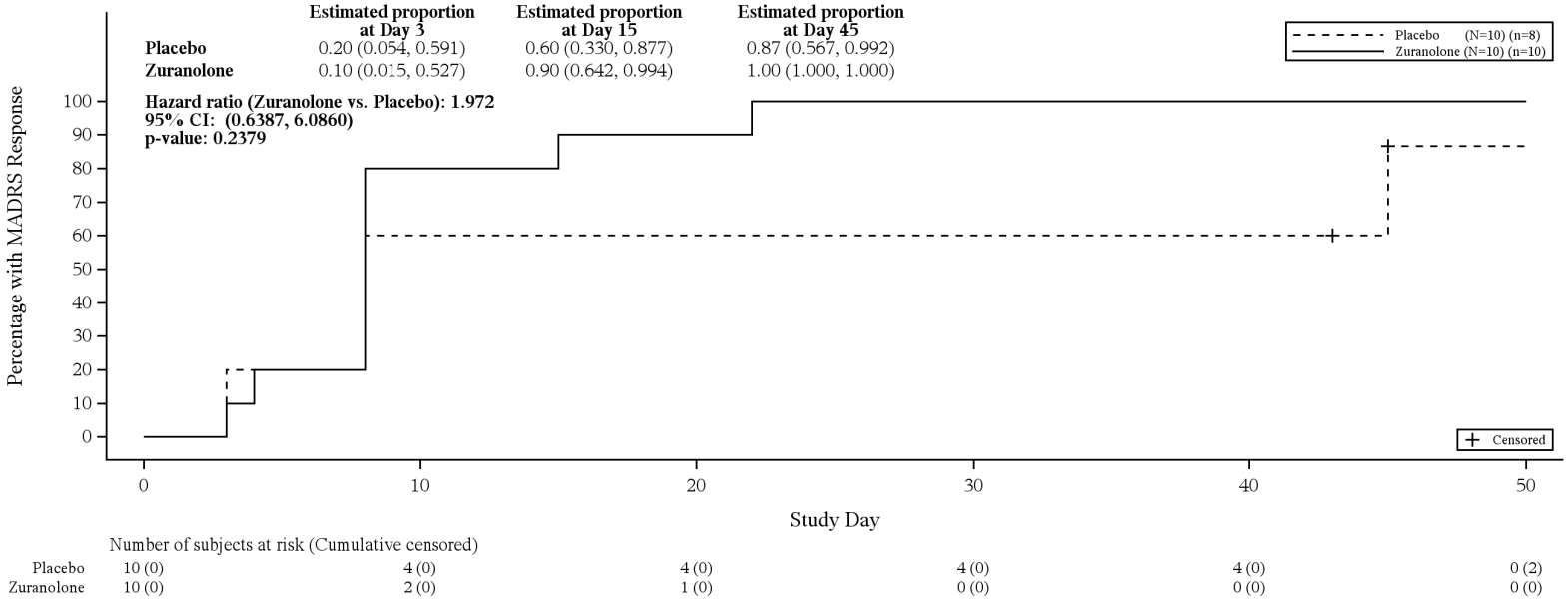
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

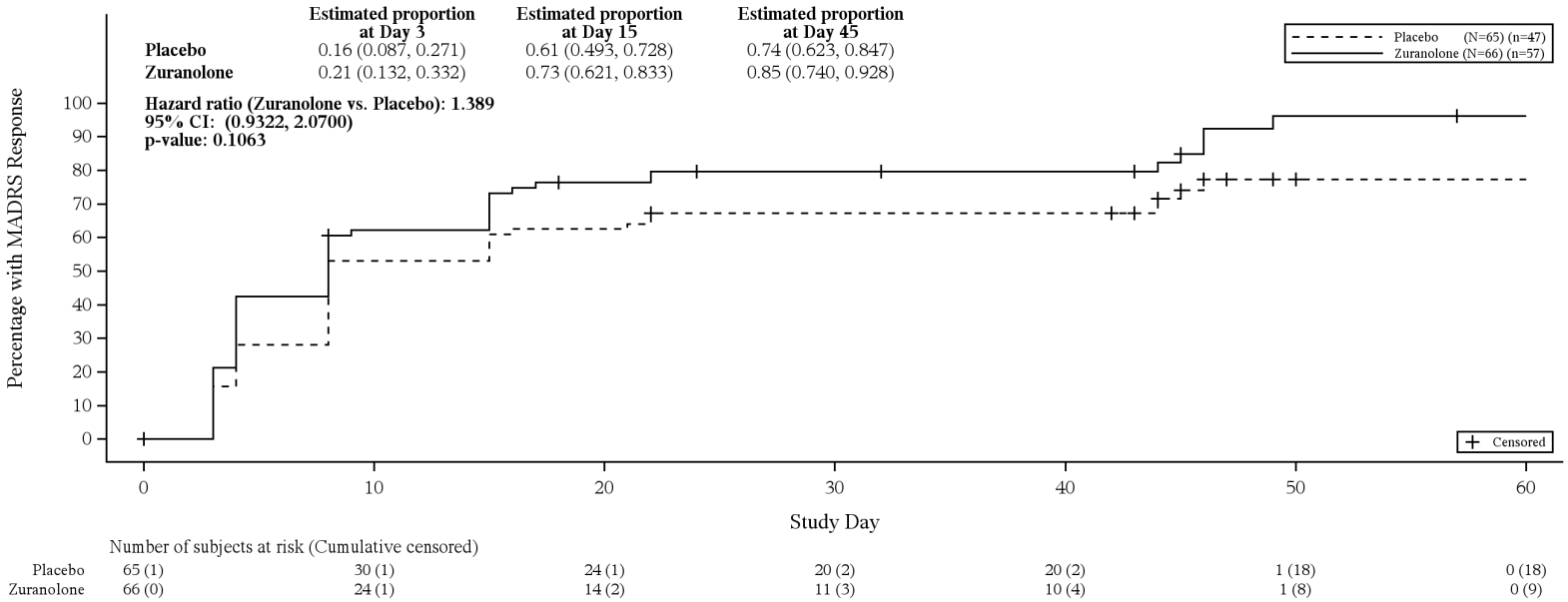
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

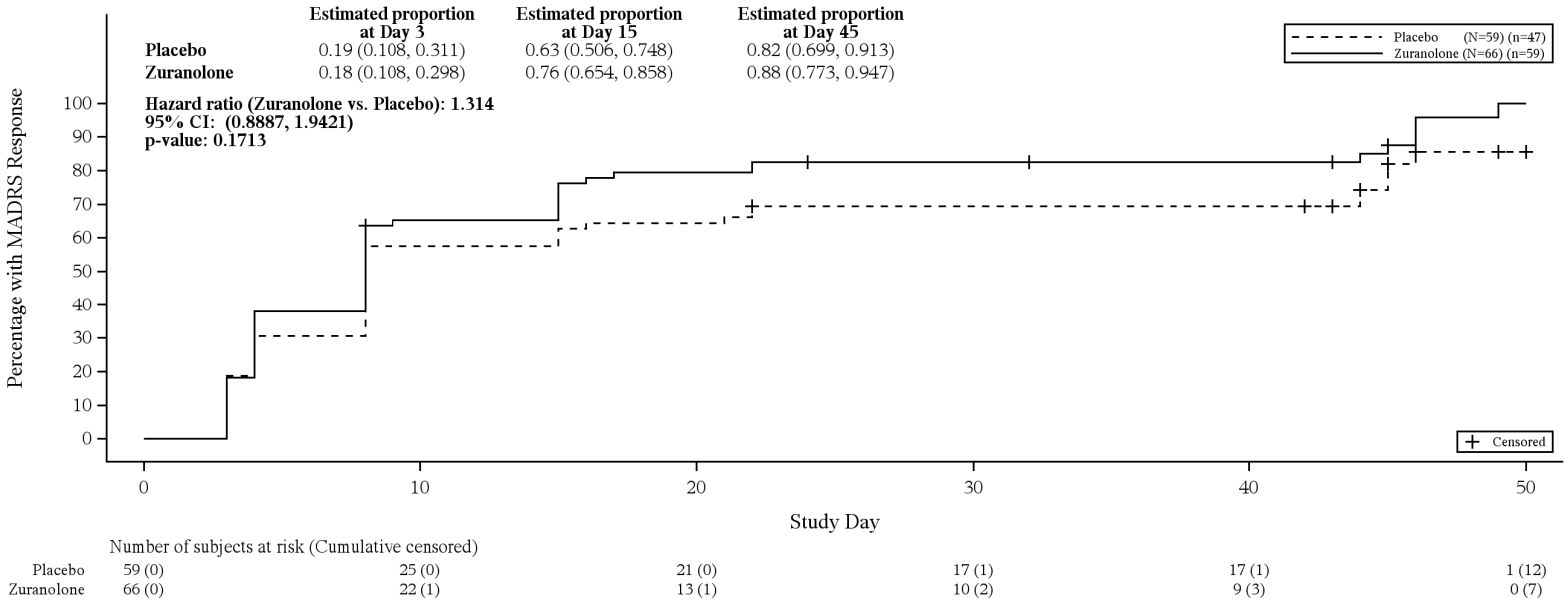
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

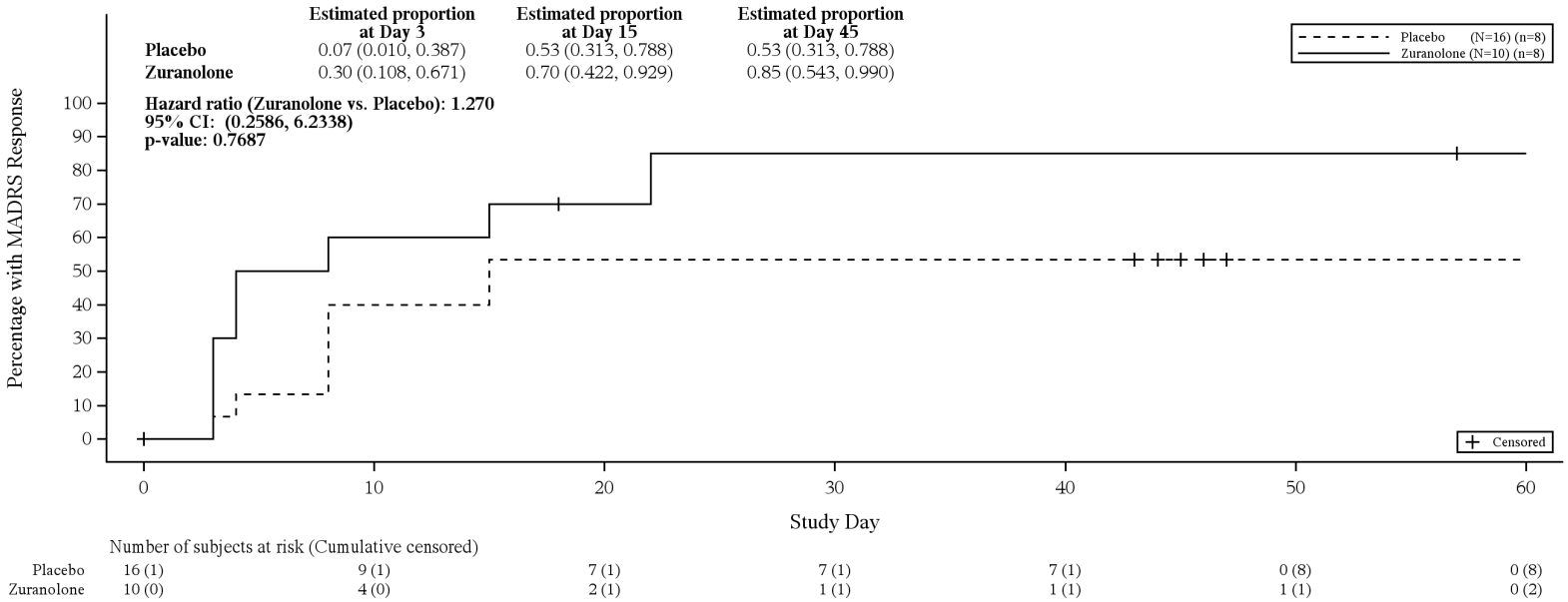
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Number of subjects at risk (Cumulative censored)

Placebo	16 (1)	9 (1)	7 (1)	7 (1)	7 (1)	0 (8)	0 (8)
Zuranolone	10 (0)	4 (0)	2 (1)	1 (1)	1 (1)	1 (1)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS response is defined as 50% or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-201-by.sas:f-madrs-resp50-tte-201-by-itta.rtf **Run Date:** 08JAN2026

4.2.3 Remission

4.2.3.1 Responder-Analysen

4.2.3.1 .1 ITT-Population

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with a remission, n (%) [2]	7 (9.3)	18 (23.7)
Number of subjects with missing evaluation, n (%)	1 (1.3)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		2.472
95% CI for the RR		(1.102, 5.549)
p-value for RR		0.0282
OR - Odds Ratio (Zuranolone vs. Placebo)		2.874
95% CI for the OR		(1.108, 7.459)
p-value for OR		0.0300
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.135
95% CI for the ARR		(0.017, 0.253)
p-value for ARR		0.0249

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-ovr.sas:t-madrs-remi-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with a remission, n (%) [2]	21 (28.0)	28 (36.8)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.254
95% CI for the RR		(0.785, 2.003)
p-value for RR		0.3443
OR - Odds Ratio (Zuranolone vs. Placebo)		1.416
95% CI for the OR		(0.706, 2.842)
p-value for OR		0.3270
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.086
95% CI for the ARR		(-0.063, 0.235)
p-value for ARR		0.2586

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-ovr.sas:t-madrs-remi-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with a remission, n (%) [2]	22 (29.3)	40 (52.6)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.778
95% CI for the RR		(1.182, 2.675)
p-value for RR		0.0058
OR - Odds Ratio (Zuranolone vs. Placebo)		2.543
95% CI for the OR		(1.292, 5.006)
p-value for OR		0.0069
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.227
95% CI for the ARR		(0.073, 0.380)
p-value for ARR		0.0038

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-ovr.sas:t-madrs-remi-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with a remission, n (%) [2]	23 (30.7)	39 (51.3)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.650
95% CI for the RR		(1.100, 2.476)
p-value for RR		0.0154
OR - Odds Ratio (Zuranolone vs. Placebo)		2.266
95% CI for the OR		(1.150, 4.465)
p-value for OR		0.0181
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.200
95% CI for the ARR		(0.045, 0.354)
p-value for ARR		0.0112

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-ovr.sas:t-madrs-remi-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a remission, n (%) [2]	26 (34.7)	43 (56.6)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.593
95% CI for the RR		(1.101, 2.305)
p-value for RR		0.0135
OR - Odds Ratio (Zuranolone vs. Placebo)		2.349
95% CI for the OR		(1.204, 4.583)
p-value for OR		0.0123
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.212
95% CI for the ARR		(0.056, 0.368)
p-value for ARR		0.0079

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-ovr.sas:t-madrs-remi-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.2.3.1 .2 Subgruppen

4.2.3.1 .2 .1 Interaktionstest

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	22 (29.3)	40 (52.6)	
Number of subjects with response at Day 45, n (%)	26 (34.7)	43 (56.6)	
Age Group (years)			0.5795
Day 15			
18 - 24, n / N (%)	9/25 (36.0)	10/17 (58.8)	
25 - 45, n / N (%)	13/50 (26.0)	30/59 (50.8)	
Day 45			
18 - 24, n / N (%)	8/25 (32.0)	7/17 (41.2)	
25 - 45, n / N (%)	18/50 (36.0)	36/59 (61.0)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS remission is defined as MADRS total score <=10.
NOTE 3: n / N (%) = number of evaluable subjects with remission in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-int.sas:t-madrs-remi-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.3700
Day 15			
<28, n / N (%)	7/22 (31.8)	15/30 (50.0)	
>=28, n / N (%)	15/53 (28.3)	25/46 (54.3)	
Day 45			
<28, n / N (%)	8/22 (36.4)	16/30 (53.3)	
>=28, n / N (%)	18/53 (34.0)	27/46 (58.7)	
Race Group (Black or African American, White)			0.8260
Day 15			
Black or African American, n / N (%)	8/32 (25.0)	16/31 (51.6)	
White, n / N (%)	13/40 (32.5)	23/44 (52.3)	
Day 45			
Black or African American, n / N (%)	10/32 (31.3)	14/31 (45.2)	
White, n / N (%)	15/40 (37.5)	28/44 (63.6)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS remission is defined as MADRS total score <=10.
NOTE 3: n / N (%) = number of evaluable subjects with remission in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-int.sas:t-madrs-remi-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.8305
Day 15			
Yes, n / N (%)	5/13 (38.5)	12/16 (75.0)	
No, n / N (%)	17/62 (27.4)	28/60 (46.7)	
Day 45			
Yes, n / N (%)	5/13 (38.5)	11/16 (68.8)	
No, n / N (%)	21/62 (33.9)	32/60 (53.3)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS remission is defined as MADRS total score <=10.
NOTE 3: n / N (%) = number of evaluable subjects with remission in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-int.sas:t-madrs-remi-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.8864(a) 0.0961(b) 0.0560(c)
Day 15			
<=24.9, n / N (%)	6/21 (28.6)	7/13 (53.8)	
25-29.9, n / N (%)	3/20 (15.0)	12/21 (57.1)	
>=30, n / N (%)	13/34 (38.2)	21/42 (50.0)	
Day 45			
<=24.9, n / N (%)	6/21 (28.6)	9/13 (69.2)	
25-29.9, n / N (%)	7/20 (35.0)	15/21 (71.4)	
>=30, n / N (%)	13/34 (38.2)	19/42 (45.2)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS remission is defined as MADRS total score <=10.
NOTE 3: n / N (%) = number of evaluable subjects with remission in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-int.sas:t-madrs-remi-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.8038
Day 15			
3rd Trimester, n / N (%)	9/32 (28.1)	17/32 (53.1)	
Postpartum, n / N (%)	13/43 (30.2)	23/44 (52.3)	
Day 45			
3rd Trimester, n / N (%)	11/32 (34.4)	19/32 (59.4)	
Postpartum, n / N (%)	15/43 (34.9)	24/44 (54.5)	
Family History of PPD			0.6991
Day 15			
Yes, n / N (%)	3/10 (30.0)	6/10 (60.0)	
No/Unknown, n / N (%)	19/65 (29.2)	34/66 (51.5)	
Day 45			
Yes, n / N (%)	4/10 (40.0)	6/10 (60.0)	
No/Unknown, n / N (%)	22/65 (33.8)	37/66 (56.1)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS remission is defined as MADRS total score <=10.
NOTE 3: n / N (%) = number of evaluable subjects with remission in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-int.sas:t-madrs-remi-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.1346
Day 15			
1st Episode, n / N (%)	20/59 (33.9)	35/66 (53.0)	
Recurrent Episode, n / N (%)	2/16 (12.5)	5/10 (50.0)	
Day 45			
1st Episode, n / N (%)	23/59 (39.0)	37/66 (56.1)	
Recurrent Episode, n / N (%)	3/16 (18.8)	6/10 (60.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	3/8 (37.5)	5/10 (50.0)	
>=20, n / N (%)	19/67 (28.4)	35/66 (53.0)	
Day 45			
<20, n / N (%)	5/8 (62.5)	5/10 (50.0)	
>=20, n / N (%)	21/67 (31.3)	38/66 (57.6)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS remission is defined as MADRS total score <=10.
NOTE 3: n / N (%) = number of evaluable subjects with remission in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-int.sas:t-madrs-remi-201-int-itta.rtf **Run Date:** 29JUL2025

4.2.3.1 .2 .2 Subgruppenanalysen

4.2.3.1 .2 .2 .1 Alter

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 3		
Number of subjects with a remission, n (%) [2]	4 (16.0)	6 (35.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.283
95% CI for the RR		(0.768, 6.783)
p-value for RR		0.1374
Day 8		
Number of subjects with a remission, n (%) [2]	4 (16.0)	5 (29.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.902
95% CI for the RR		(0.580, 6.237)
p-value for RR		0.2885

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-age-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-201B - ITT population

Page: 2 of 6

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 15		
Number of subjects with a remission, n (%) [2]	9 (36.0)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.691
95% CI for the RR		(0.869, 3.289)
p-value for RR		0.1218
Day 21		
Number of subjects with a remission, n (%) [2]	9 (36.0)	9 (52.9)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.522
95% CI for the RR		(0.766, 3.024)
p-value for RR		0.2305

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-age-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 45		
Number of subjects with a remission, n (%) [2]	8 (32.0)	7 (41.2)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.332
95% CI for the RR		(0.597, 2.970)
p-value for RR		0.4840

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-age-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 3		
Number of subjects with a remission, n (%) [2]	3 (6.0)	12 (20.3)
Number of subjects with missing evaluation, n (%)	1 (2.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		3.179
95% CI for the RR		(0.946, 10.687)
p-value for RR		0.0615
Day 8		
Number of subjects with a remission, n (%) [2]	17 (34.0)	23 (39.0)
Number of subjects with missing evaluation, n (%)	1 (2.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.075
95% CI for the RR		(0.648, 1.784)
p-value for RR		0.7786

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-age-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 15		
Number of subjects with a remission, n (%) [2]	13 (26.0)	30 (50.8)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.834
95% CI for the RR		(1.075, 3.131)
p-value for RR		0.0261
Day 21		
Number of subjects with a remission, n (%) [2]	14 (28.0)	30 (50.8)
Number of subjects with missing evaluation, n (%)	2 (4.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.703
95% CI for the RR		(1.019, 2.848)
p-value for RR		0.0423

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-age-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 45		
Number of subjects with a remission, n (%) [2]	18 (36.0)	36 (61.0)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.590
95% CI for the RR		(1.035, 2.442)
p-value for RR		0.0343

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-age-itta.rtf **Run Date:** 31JUL2025

4.2.3.1 .2 .2 .2 Schwere der Erkrankung

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 3		
Number of subjects with a remission, n (%) [2]	3 (13.6)	7 (23.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.844
95% CI for the RR		(0.536, 6.347)
p-value for RR		0.3320
Day 8		
Number of subjects with a remission, n (%) [2]	7 (31.8)	9 (30.0)
Number of subjects with missing evaluation, n (%)	0	1 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.016
95% CI for the RR		(0.408, 2.531)
p-value for RR		0.9729

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-hamd-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 15		
Number of subjects with a remission, n (%) [2]	7 (31.8)	15 (50.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.693
95% CI for the RR		(0.743, 3.857)
p-value for RR		0.2099
Day 21		
Number of subjects with a remission, n (%) [2]	9 (40.9)	11 (36.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.966
95% CI for the RR		(0.395, 2.363)
p-value for RR		0.9392

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-hamd-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 45		
Number of subjects with a remission, n (%) [2]	8 (36.4)	16 (53.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.580
95% CI for the RR		(0.725, 3.446)
p-value for RR		0.2498

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-hamd-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 3		
Number of subjects with a remission, n (%) [2]	4 (7.5)	11 (23.9)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.010
95% CI for the RR		(1.017, 8.908)
p-value for RR		0.0465
Day 8		
Number of subjects with a remission, n (%) [2]	14 (26.4)	19 (41.3)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.485
95% CI for the RR		(0.836, 2.638)
p-value for RR		0.1770

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-hamd-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 15		
Number of subjects with a remission, n (%) [2]	15 (28.3)	25 (54.3)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.824
95% CI for the RR		(1.100, 3.025)
p-value for RR		0.0198
Day 21		
Number of subjects with a remission, n (%) [2]	14 (26.4)	28 (60.9)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.189
95% CI for the RR		(1.318, 3.635)
p-value for RR		0.0025

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-hamd-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 45		
Number of subjects with a remission, n (%) [2]	18 (34.0)	27 (58.7)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.642
95% CI for the RR		(1.047, 2.575)
p-value for RR		0.0308

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-hamd-itta.rtf **Run Date:** 31JUL2025

4.2.3.1 .2 .2 .3 Abstammung

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-201B - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 3		
Number of subjects with a remission, n (%) [2]	2 (6.3)	5 (16.1)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.710
95% CI for the RR		(0.578, 12.706)
p-value for RR		0.2060
Day 8		
Number of subjects with a remission, n (%) [2]	7 (21.9)	11 (35.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.754
95% CI for the RR		(0.804, 3.825)
p-value for RR		0.1579

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-race-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-201B - ITT population

Page: 2 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 15		
Number of subjects with a remission, n (%) [2]	8 (25.0)	16 (51.6)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.088
95% CI for the RR		(1.073, 4.065)
p-value for RR		0.0303
Day 21		
Number of subjects with a remission, n (%) [2]	7 (21.9)	13 (41.9)
Number of subjects with missing evaluation, n (%)	1 (3.1)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.039
95% CI for the RR		(0.976, 4.257)
p-value for RR		0.0579

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-race-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-201B - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 45		
Number of subjects with a remission, n (%) [2]	10 (31.3)	14 (45.2)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.532
95% CI for the RR		(0.816, 2.877)
p-value for RR		0.1842

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-race-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-201B - ITT population

Page: 4 of 6

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 3		
Number of subjects with a remission, n (%) [2]	5 (12.5)	13 (29.5)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		2.269
95% CI for the RR		(0.901, 5.716)
p-value for RR		0.0822
Day 8		
Number of subjects with a remission, n (%) [2]	13 (32.5)	17 (38.6)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.121
95% CI for the RR		(0.625, 2.012)
p-value for RR		0.7010

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-race-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-201B - ITT population

Page: 5 of 6

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 15		
Number of subjects with a remission, n (%) [2]	13 (32.5)	23 (52.3)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.594
95% CI for the RR		(0.956, 2.659)
p-value for RR		0.0741
Day 21		
Number of subjects with a remission, n (%) [2]	15 (37.5)	26 (59.1)
Number of subjects with missing evaluation, n (%)	1 (2.5)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.532
95% CI for the RR		(0.956, 2.454)
p-value for RR		0.0762

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-race-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 45		
Number of subjects with a remission, n (%) [2]	15 (37.5)	28 (63.6)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.640
95% CI for the RR		(1.044, 2.574)
p-value for RR		0.0317

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-race-itta.rtf **Run Date:** 31JUL2025

4.2.3.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 3		
Number of subjects with a remission, n (%) [2]	2 (15.4)	5 (31.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.014
95% CI for the RR		(0.467, 8.690)
p-value for RR		0.3482
Day 8		
Number of subjects with a remission, n (%) [2]	5 (38.5)	5 (31.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.807
95% CI for the RR		(0.298, 2.187)
p-value for RR		0.6728

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-adt-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 15		
Number of subjects with a remission, n (%) [2]	5 (38.5)	12 (75.0)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.933
95% CI for the RR		(0.917, 4.073)
p-value for RR		0.0832
Day 21		
Number of subjects with a remission, n (%) [2]	4 (30.8)	11 (68.8)
Number of subjects with missing evaluation, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.219
95% CI for the RR		(0.918, 5.359)
p-value for RR		0.0766

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-adt-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 45		
Number of subjects with a remission, n (%) [2]	5 (38.5)	11 (68.8)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.779
95% CI for the RR		(0.826, 3.833)
p-value for RR		0.1414

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-adt-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 3		
Number of subjects with a remission, n (%) [2]	5 (8.1)	13 (21.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.624
95% CI for the RR		(0.994, 6.928)
p-value for RR		0.0515
Day 8		
Number of subjects with a remission, n (%) [2]	16 (25.8)	23 (38.3)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.441
95% CI for the RR		(0.844, 2.461)
p-value for RR		0.1804

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-adt-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 15		
Number of subjects with a remission, n (%) [2]	17 (27.4)	28 (46.7)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.665
95% CI for the RR		(1.014, 2.733)
p-value for RR		0.0438
Day 21		
Number of subjects with a remission, n (%) [2]	19 (30.6)	28 (46.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.481
95% CI for the RR		(0.927, 2.366)
p-value for RR		0.1007

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-adt-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 45		
Number of subjects with a remission, n (%) [2]	21 (33.9)	32 (53.3)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.547
95% CI for the RR		(1.009, 2.374)
p-value for RR		0.0456

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-adt-itta.rtf **Run Date:** 31JUL2025

4.2.3.1 .2 .2 .5 BMI

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 3		
Number of subjects with a remission, n (%) [2]	2 (9.5)	3 (23.1)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.42
95% CI for the RR		(0.465, 12.618)
p-value for RR		0.2931
Day 8		
Number of subjects with a remission, n (%) [2]	4 (19.0)	5 (38.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.02
95% CI for the RR		(0.660, 6.177)
p-value for RR		0.2180

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-bmi-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 15		
Number of subjects with a remission, n (%) [2]	6 (28.6)	7 (53.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.88
95% CI for the RR		(0.811, 4.378)
p-value for RR		0.1406
Day 21		
Number of subjects with a remission, n (%) [2]	4 (19.0)	7 (53.8)
Number of subjects with missing evaluation, n (%)	2 (9.5)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.83
95% CI for the RR		(1.024, 7.802)
p-value for RR		0.0448

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-bmi-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 45		
Number of subjects with a remission, n (%) [2]	6 (28.6)	9 (69.2)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.42
95% CI for the RR		(1.125, 5.219)
p-value for RR		0.0238

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-bmi-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 3		
Number of subjects with a remission, n (%) [2]	0	7 (33.3)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		14.32
95% CI for the RR		(0.871, 235.355)
p-value for RR		0.0624
Day 8		
Number of subjects with a remission, n (%) [2]	4 (20.0)	11 (52.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.62
95% CI for the RR		(0.996, 6.886)
p-value for RR		0.0509

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-bmi-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 15		
Number of subjects with a remission, n (%) [2]	3 (15.0)	12 (57.1)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		3.81
95% CI for the RR		(1.259, 11.526)
p-value for RR		0.0179
Day 21		
Number of subjects with a remission, n (%) [2]	6 (30.0)	12 (57.1)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.90
95% CI for the RR		(0.886, 4.094)
p-value for RR		0.0988

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-bmi-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 45		
Number of subjects with a remission, n (%) [2]	7 (35.0)	15 (71.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.04
95% CI for the RR		(1.059, 3.931)
p-value for RR		0.0330

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-bmi-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 3		
Number of subjects with a remission, n (%) [2]	5 (14.7)	8 (19.0)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.30
95% CI for the RR		(0.466, 3.598)
p-value for RR		0.6197
Day 8		
Number of subjects with a remission, n (%) [2]	13 (38.2)	12 (28.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.75
95% CI for the RR		(0.394, 1.419)
p-value for RR		0.3732

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-bmi-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 15		
Number of subjects with a remission, n (%) [2]	13 (38.2)	21 (50.0)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.31
95% CI for the RR		(0.775, 2.207)
p-value for RR		0.3151
Day 21		
Number of subjects with a remission, n (%) [2]	13 (38.2)	20 (47.6)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.25
95% CI for the RR		(0.732, 2.120)
p-value for RR		0.4188

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-bmi-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 45		
Number of subjects with a remission, n (%) [2]	13 (38.2)	19 (45.2)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.18
95% CI for the RR		(0.688, 2.033)
p-value for RR		0.5427

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-bmi-itta.rtf **Run Date:** 31JUL2025

4.2.3.1 .2 .2 .6 Beginn der PPD

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 3		
Number of subjects with a remission, n (%) [2]	1 (3.1)	6 (18.8)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		5.973
95% CI for the RR		(0.738, 48.366)
p-value for RR		0.0940
Day 8		
Number of subjects with a remission, n (%) [2]	9 (28.1)	12 (37.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.284
95% CI for the RR		(0.632, 2.611)
p-value for RR		0.4898

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-onset-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 15		
Number of subjects with a remission, n (%) [2]	9 (28.1)	17 (53.1)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.845
95% CI for the RR		(0.975, 3.492)
p-value for RR		0.0600
Day 21		
Number of subjects with a remission, n (%) [2]	11 (34.4)	18 (56.3)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.651
95% CI for the RR		(0.950, 2.871)
p-value for RR		0.0754

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-onset-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 45		
Number of subjects with a remission, n (%) [2]	11 (34.4)	19 (59.4)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.697
95% CI for the RR		(0.976, 2.951)
p-value for RR		0.0610

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-onset-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 3		
Number of subjects with a remission, n (%) [2]	6 (14.0)	12 (27.3)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.864
95% CI for the RR		(0.760, 4.571)
p-value for RR		0.1735
Day 8		
Number of subjects with a remission, n (%) [2]	12 (27.9)	16 (36.4)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.218
95% CI for the RR		(0.654, 2.270)
p-value for RR		0.5344

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-onset-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 15		
Number of subjects with a remission, n (%) [2]	13 (30.2)	23 (52.3)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.713
95% CI for the RR		(1.006, 2.918)
p-value for RR		0.0475
Day 21		
Number of subjects with a remission, n (%) [2]	12 (27.9)	21 (47.7)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.669
95% CI for the RR		(0.939, 2.968)
p-value for RR		0.0810

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-onset-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 45		
Number of subjects with a remission, n (%) [2]	15 (34.9)	24 (54.5)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.525
95% CI for the RR		(0.935, 2.490)
p-value for RR		0.0912

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-onset-itta.rtf **Run Date:** 31JUL2025

4.2.3.1 .2 .2 .7 PPD in der Familie

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 3		
Number of subjects with a remission, n (%) [2]	0	1 (10.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.137, 65.903)
p-value for RR		0.4858
Day 8		
Number of subjects with a remission, n (%) [2]	2 (20.0)	5 (50.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.50
95% CI for the RR		(0.625, 9.996)
p-value for RR		0.1950

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-fhist-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 6

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 15		
Number of subjects with a remission, n (%) [2]	3 (30.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.00
95% CI for the RR		(0.684, 5.851)
p-value for RR		0.2057
Day 21		
Number of subjects with a remission, n (%) [2]	2 (20.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.50
95% CI for the RR		(0.950, 12.898)
p-value for RR		0.0598

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-fhist-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 45		
Number of subjects with a remission, n (%) [2]	4 (40.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.50
95% CI for the RR		(0.602, 3.735)
p-value for RR		0.3837

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-fhist-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 3		
Number of subjects with a remission, n (%) [2]	7 (10.8)	17 (25.8)
Number of subjects with missing evaluation, n (%)	1 (1.5)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.39
95% CI for the RR		(1.063, 5.381)
p-value for RR		0.0350
Day 8		
Number of subjects with a remission, n (%) [2]	19 (29.2)	23 (34.8)
Number of subjects with missing evaluation, n (%)	1 (1.5)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.19
95% CI for the RR		(0.722, 1.969)
p-value for RR		0.4924

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-fhist-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 15		
Number of subjects with a remission, n (%) [2]	19 (29.2)	34 (51.5)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.76
95% CI for the RR		(1.130, 2.750)
p-value for RR		0.0125
Day 21		
Number of subjects with a remission, n (%) [2]	21 (32.3)	32 (48.5)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.50
95% CI for the RR		(0.975, 2.309)
p-value for RR		0.0648

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-fhist-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 45		
Number of subjects with a remission, n (%) [2]	22 (33.8)	37 (56.1)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.66
95% CI for the RR		(1.109, 2.474)
p-value for RR		0.0137

NOTE 1: Normal approximation method has been used to estimate relative risk and it's p-value.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-fhist-itta.rtf **Run Date:** 31JUL2025

4.2.3.1 .2 .2 .8 PPD in der Anamnese

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 6

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 3		
Number of subjects with a remission, n (%) [2]	6 (10.2)	15 (22.7)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.225
95% CI for the RR		(0.924, 5.362)
p-value for RR		0.0746
Day 8		
Number of subjects with a remission, n (%) [2]	18 (30.5)	23 (34.8)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.137
95% CI for the RR		(0.685, 1.889)
p-value for RR		0.6189

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-hist-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-201B - ITT population

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 15		
Number of subjects with a remission, n (%) [2]	20 (33.9)	35 (53.0)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.558
95% CI for the RR		(1.021, 2.377)
p-value for RR		0.0399
Day 21		
Number of subjects with a remission, n (%) [2]	20 (33.9)	32 (48.5)
Number of subjects with missing evaluation, n (%)	1 (1.7)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.424
95% CI for the RR		(0.921, 2.201)
p-value for RR		0.1114

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-hist-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 45		
Number of subjects with a remission, n (%) [2]	23 (39.0)	37 (56.1)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.432
95% CI for the RR		(0.973, 2.108)
p-value for RR		0.0689

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-hist-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 3		
Number of subjects with a remission, n (%) [2]	1 (6.3)	3 (30.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.816
95% CI for the RR		(0.426, 34.219)
p-value for RR		0.2314
Day 8		
Number of subjects with a remission, n (%) [2]	3 (18.8)	5 (50.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.120
95% CI for the RR		(0.519, 8.653)
p-value for RR		0.2950

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-hist-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 15		
Number of subjects with a remission, n (%) [2]	2 (12.5)	5 (50.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.180
95% CI for the RR		(0.610, 16.572)
p-value for RR		0.1696
Day 21		
Number of subjects with a remission, n (%) [2]	3 (18.8)	7 (70.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.968
95% CI for the RR		(0.868, 10.150)
p-value for RR		0.0829

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-hist-itta.rtf **Run Date:** 31JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 45		
Number of subjects with a remission, n (%) [2]	3 (18.8)	6 (60.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.544
95% CI for the RR		(0.717, 9.032)
p-value for RR		0.1486

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline MADRS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission (defined as MADRS total score <=10). Missing MADRS total score at the visit has been imputed as "no remission". The denominator for the percentage is the number of evaluable subjects.

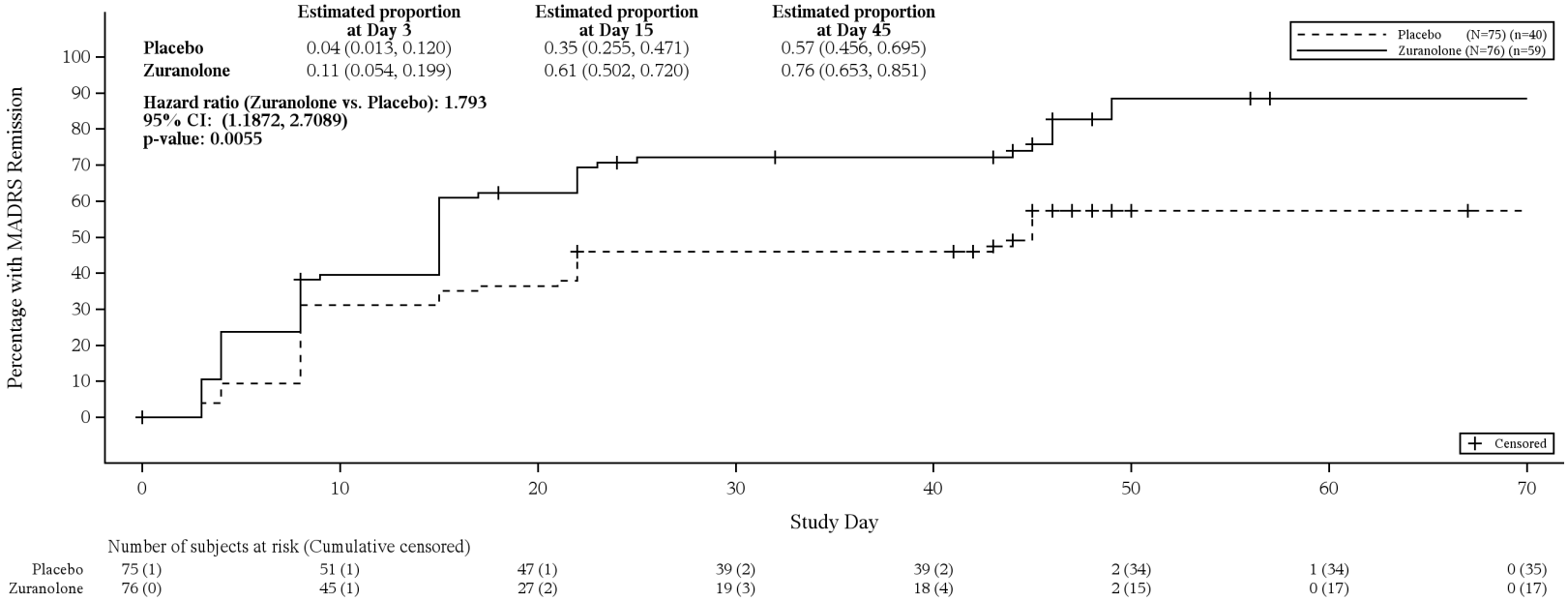
Source: biib125/v_a/germany_amnog/t-madrs-remi-201-by.sas:t-madrs-remi-201-by-hist-itta.rtf **Run Date:** 31JUL2025

4.2.3.2 TTE-Analysen

4.2.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.
NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-ovr.sas:f-madrs-remi-tte-201-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	40 (53.3)	59 (77.6)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 15.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	45.0 (22.0, NE)	15.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	45.0 (22.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.793
95% CI for the HR		(1.1872 , 2.7089)
p-value for the HR		0.0055

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-ovr.sas:t-madrs-remi-tte-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.2.3.2 .2 Subgruppen

4.2.3.2 .2 .1 Interaktionstest

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	40 (53.3)	59 (77.6)	
Age Group (years)			
18 - 24, n / N (%)	12/25 (48.0)	14/17 (82.4)	0.2101
25 - 45, n / N (%)	28/50 (56.0)	45/59 (76.3)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	11/22 (50.0)	20/30 (66.7)	0.6593
>=28, n / N (%)	29/53 (54.7)	39/46 (84.8)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	16/32 (50.0)	20/31 (64.5)	0.4055
White, n / N (%)	23/40 (57.5)	38/44 (86.4)	
Antidepressant Use at Baseline			
Yes, n / N (%)	9/13 (69.2)	14/16 (87.5)	0.9839
No, n / N (%)	31/62 (50.0)	45/60 (75.0)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with remission in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-int.sas:t-madrs-remi-tte-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	9/21 (42.9)	11/13 (84.6)	0.7563(a)
25-29.9, n / N (%)	8/20 (40.0)	17/21 (81.0)	0.0587(b)
>=30, n / N (%)	23/34 (67.6)	31/42 (73.8)	0.0203(c)
Onset of PPD			
3rd Trimester, n / N (%)	17/32 (53.1)	25/32 (78.1)	0.9818
Postpartum, n / N (%)	23/43 (53.5)	34/44 (77.3)	
Family History of PPD			
Yes, n / N (%)	5/10 (50.0)	10/10 (100.0)	0.3972
No/Unknown, n / N (%)	35/65 (53.8)	49/66 (74.2)	
History of PPD			
1st Episode, n / N (%)	36/59 (61.0)	51/66 (77.3)	0.1373
Recurrent Episode, n / N (%)	4/16 (25.0)	8/10 (80.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	6/8 (75.0)	7/10 (70.0)	NA
>=20, n / N (%)	34/67 (50.7)	52/66 (78.8)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with remission in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-int.sas:t-madrs-remi-tte-201-int-itta.rtf **Run Date:** 29JUL2025

4.2.3.2 .2 .2 Subgruppenanalysen

4.2.3.2 .2 .2 .1 Alter

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	12 (48.0)	14 (82.4)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 22.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	15.0 (3.0 , 22.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	22.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.790
95% CI for the HR		(1.2522 , 6.2156)
p-value for the HR		0.0121

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	28 (56.0)	45 (76.3)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 22.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	44.0 (15.0, NE)	15.0 (8.0 , 22.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	46.0 (22.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.443
95% CI for the HR		(0.8832 , 2.3583)
p-value for the HR		0.1432

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.2.3.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	11 (50.0)	20 (66.7)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 22.0)	8.0 (3.0 , 15.0)
50th percentile - median (95% CI)	43.0 (8.0, NE)	15.0 (8.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.492
95% CI for the HR		(0.7116 , 3.1292)
p-value for the HR		0.2894

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	29 (54.7)	39 (84.8)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 17.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	45.0 (17.0, NE)	15.0 (8.0 , 17.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	23.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.971
95% CI for the HR		(1.1882 , 3.2694)
p-value for the HR		0.0086

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.2.3.2 .2 .2 .3 Abstammung

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	16 (50.0)	20 (64.5)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 22.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	15.0 (8.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.611
95% CI for the HR		(0.8059 , 3.2194)
p-value for the HR		0.1773

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	23 (57.5)	38 (86.4)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 17.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	33.5 (8.0, NE)	15.0 (8.0 , 17.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	23.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.124
95% CI for the HR		(1.2355 , 3.6500)
p-value for the HR		0.0064

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.2.3.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	9 (69.2)	14 (87.5)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 22.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	22.0 (8.0, NE)	15.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	45.0 (8.0, NE)	15.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.639
95% CI for the HR		(0.6664 , 4.0333)
p-value for the HR		0.2818

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	31 (50.0)	45 (75.0)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 21.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	45.0 (22.0, NE)	15.0 (8.0 , 22.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	46.0 (22.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.802
95% CI for the HR		(1.1301 , 2.8732)
p-value for the HR		0.0134

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.2.3.2 .2 .2 .5 BMI

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	9 (42.9)	11 (84.6)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	11.5 (4.0 , 45.0)	8.0 (3.0 , 15.0)
50th percentile - median (95% CI)	45.0 (8.0, NE)	15.0 (4.0 , 23.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	23.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.377
95% CI for the HR		(1.2880 , 8.8517)
p-value for the HR		0.0133

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.
Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	8 (40.0)	17 (81.0)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	21.5 (8.0, NE)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	NE (21.0, NE)	9.0 (4.0 , 22.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	45.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.299
95% CI for the HR		(1.3654 , 7.9715)
p-value for the HR		0.0080

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.
Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	23 (67.6)	31 (73.8)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	19.5 (8.0 , 45.0)	15.0 (15.0 , 22.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	46.0 (22.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.088
95% CI for the HR		(0.6267 , 1.8880)
p-value for the HR		0.7648

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.
Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.2.3.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	17 (53.1)	25 (78.1)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 22.0)	8.0 (3.0 , 9.0)
50th percentile - median (95% CI)	22.0 (15.0, NE)	15.0 (8.0 , 25.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.891
95% CI for the HR		(0.9892 , 3.6156)
p-value for the HR		0.0540

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	23 (53.5)	34 (77.3)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 22.0)	4.0 (4.0 , 8.0)
50th percentile - median (95% CI)	45.0 (15.0, NE)	15.0 (8.0 , 17.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	44.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.798
95% CI for the HR		(1.0368 , 3.1170)
p-value for the HR		0.0367

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.2.3.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	5 (50.0)	10 (100.0)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 45.0)	8.0 (4.0 , 15.0)
50th percentile - median (95% CI)	45.0 (8.0, NE)	11.5 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		4.558
95% CI for the HR		(1.2090 , 17.1802)
p-value for the HR		0.0251

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	35 (53.8)	49 (74.2)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 15.0)	4.0 (4.0 , 8.0)
50th percentile - median (95% CI)	44.0 (17.0, NE)	15.0 (9.0 , 22.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	46.0 (22.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.634
95% CI for the HR		(1.0492 , 2.5438)
p-value for the HR		0.0298

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.2.3.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	36 (61.0)	51 (77.3)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 15.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	22.0 (15.0 , 45.0)	15.0 (9.0 , 17.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	46.0 (22.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.557
95% CI for the HR		(1.0109 , 2.3989)
p-value for the HR		0.0445

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-201-by.sas:t-madrs-remi-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	4 (25.0)	8 (80.0)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	21.0 (4.0, NE)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	NE (8.0, NE)	11.5 (3.0 , 22.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	22.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.913
95% CI for the HR		(0.7022 , 21.8009)
p-value for the HR		0.1196

NOTE 1: MADRS remission is defined as having a MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing MADRS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a MADRS remission. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline MADRS total score, and treatment.

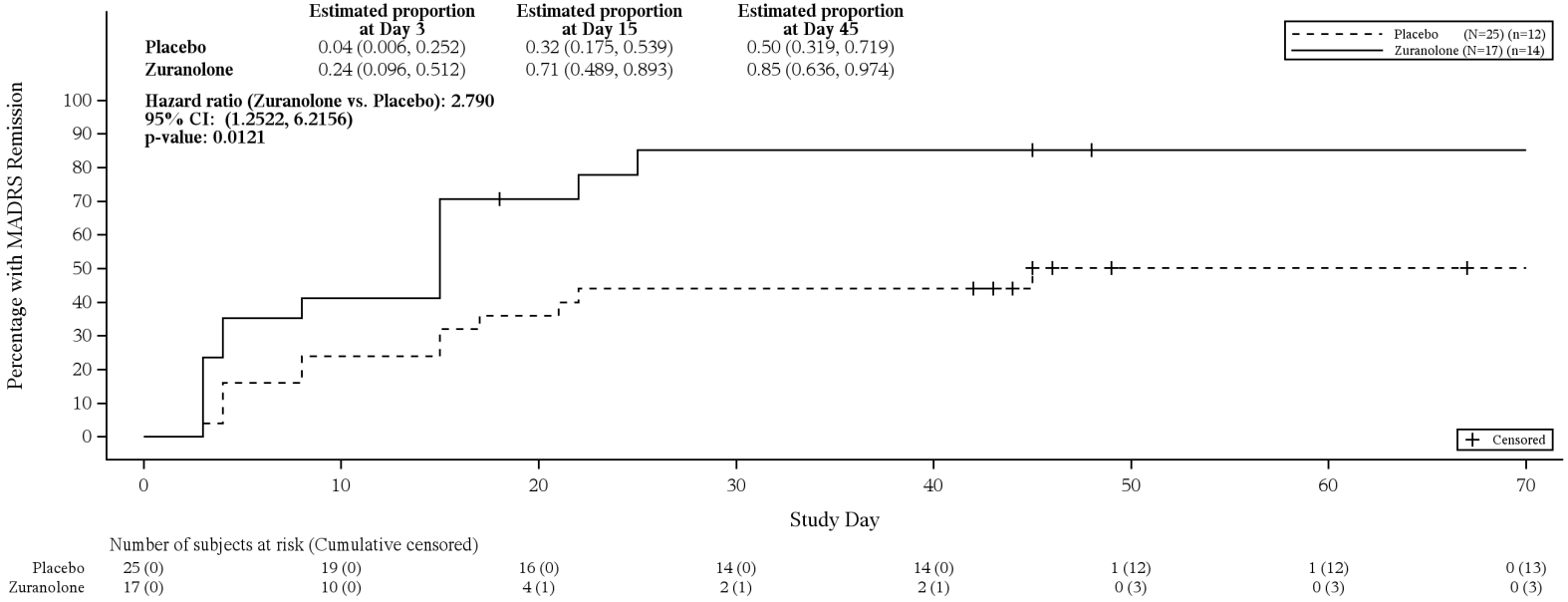
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4.2.3.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

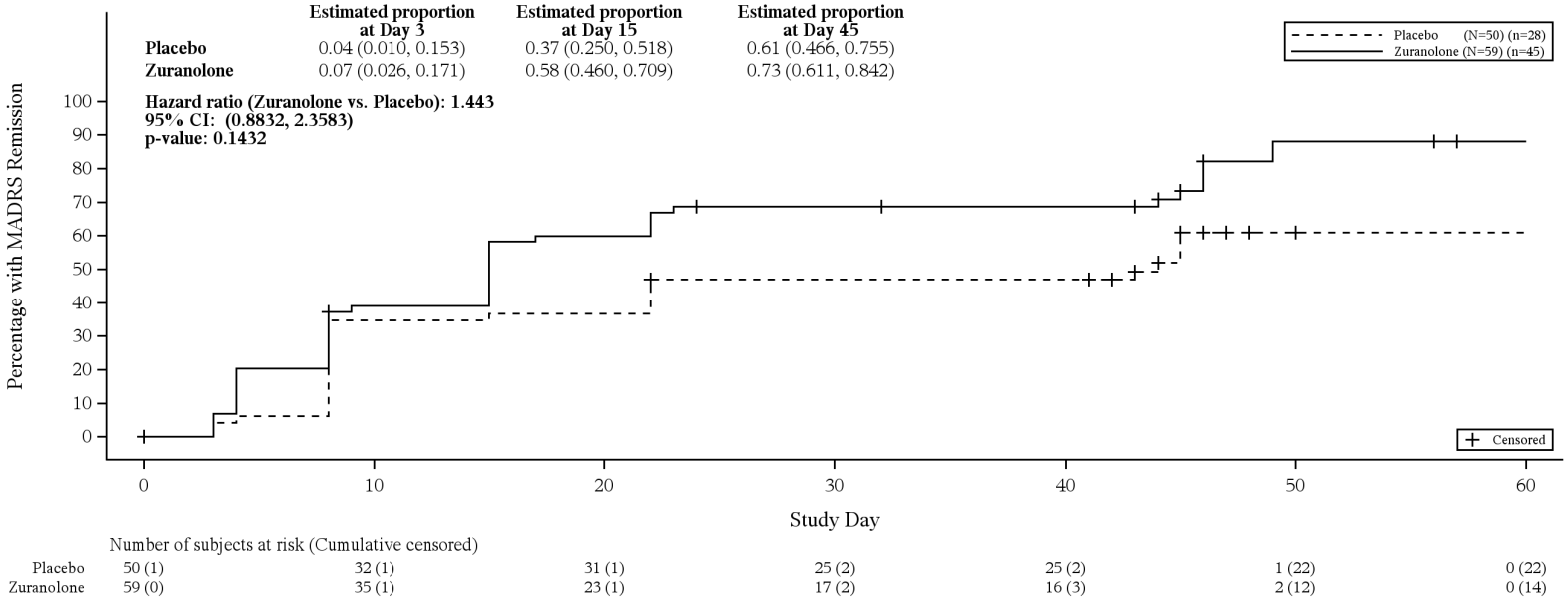
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

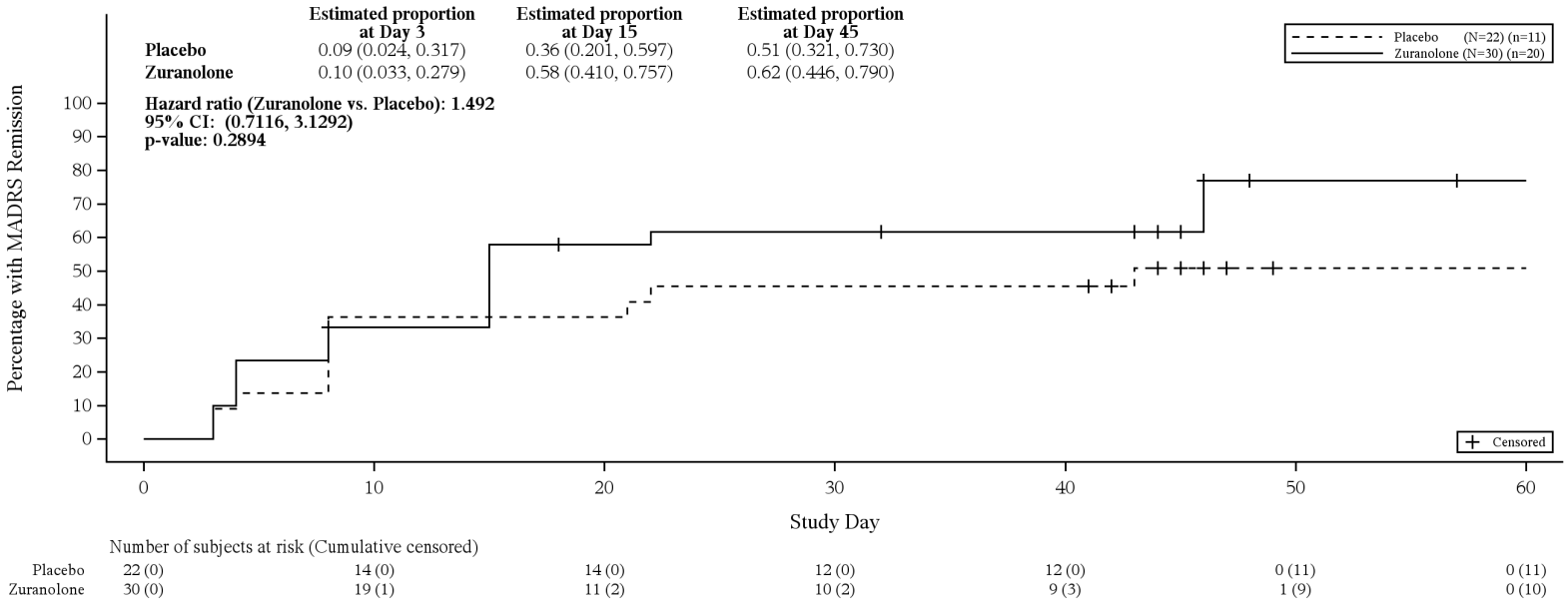
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	14 (0)	14 (0)	12 (0)	12 (0)	0 (11)	0 (11)
Zuranolone	30 (0)	19 (1)	11 (2)	10 (2)	9 (3)	1 (9)	0 (10)

Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

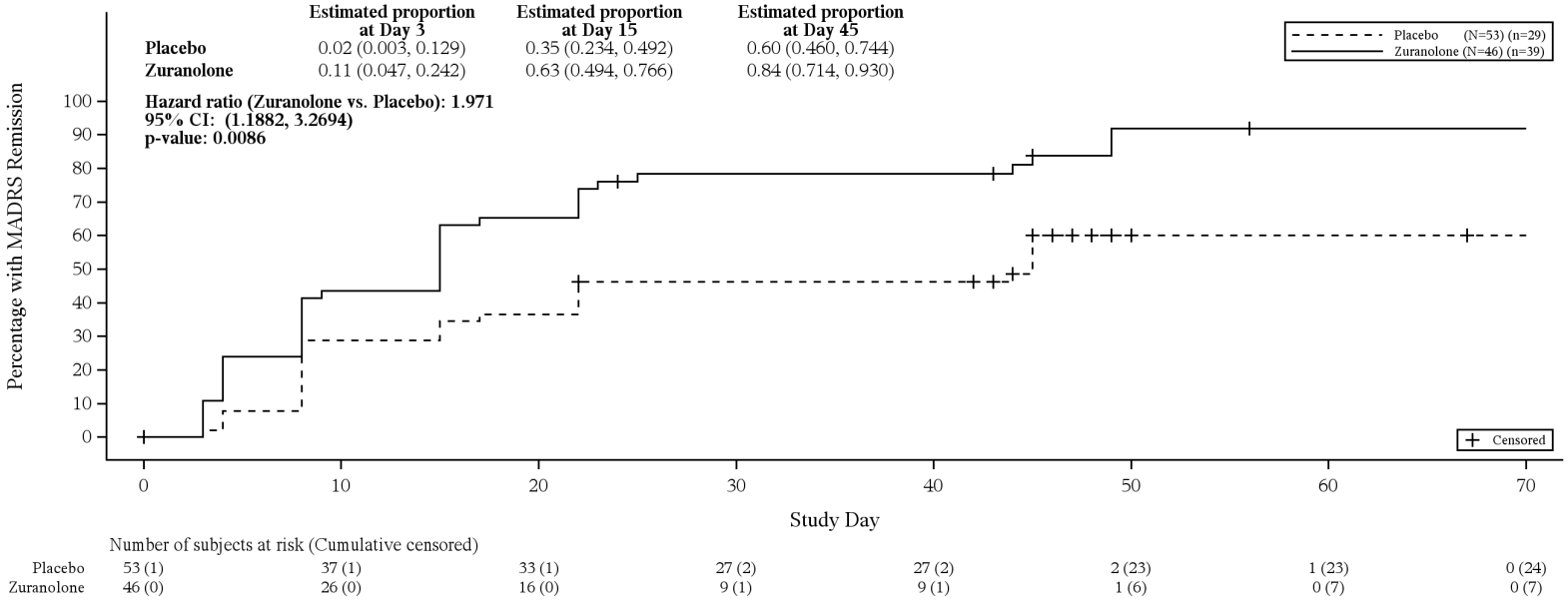
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

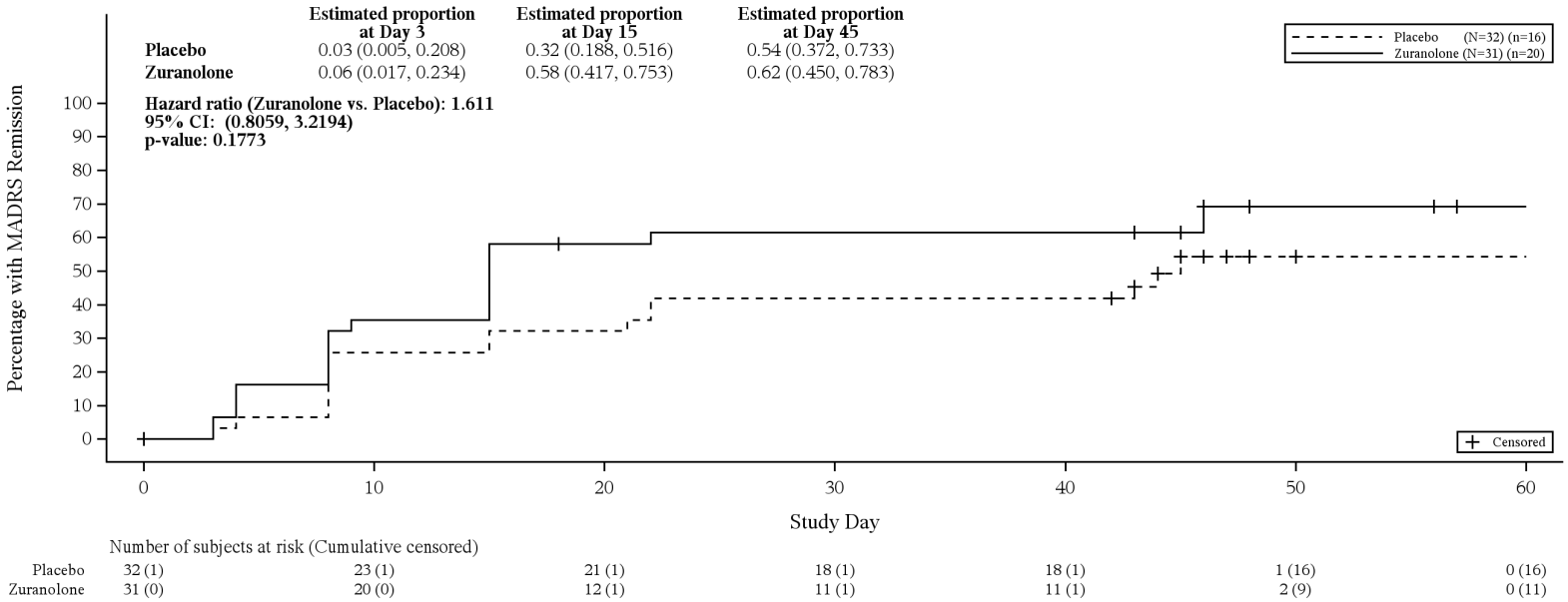
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

Page: 5 of 17

Race Group = Black or African American



Number of subjects at risk (Cumulative censored)

Placebo	32 (1)	23 (1)	21 (1)	18 (1)	18 (1)	1 (16)	0 (16)
Zuranolone	31 (0)	20 (0)	12 (1)	11 (1)	11 (1)	2 (9)	0 (11)

Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

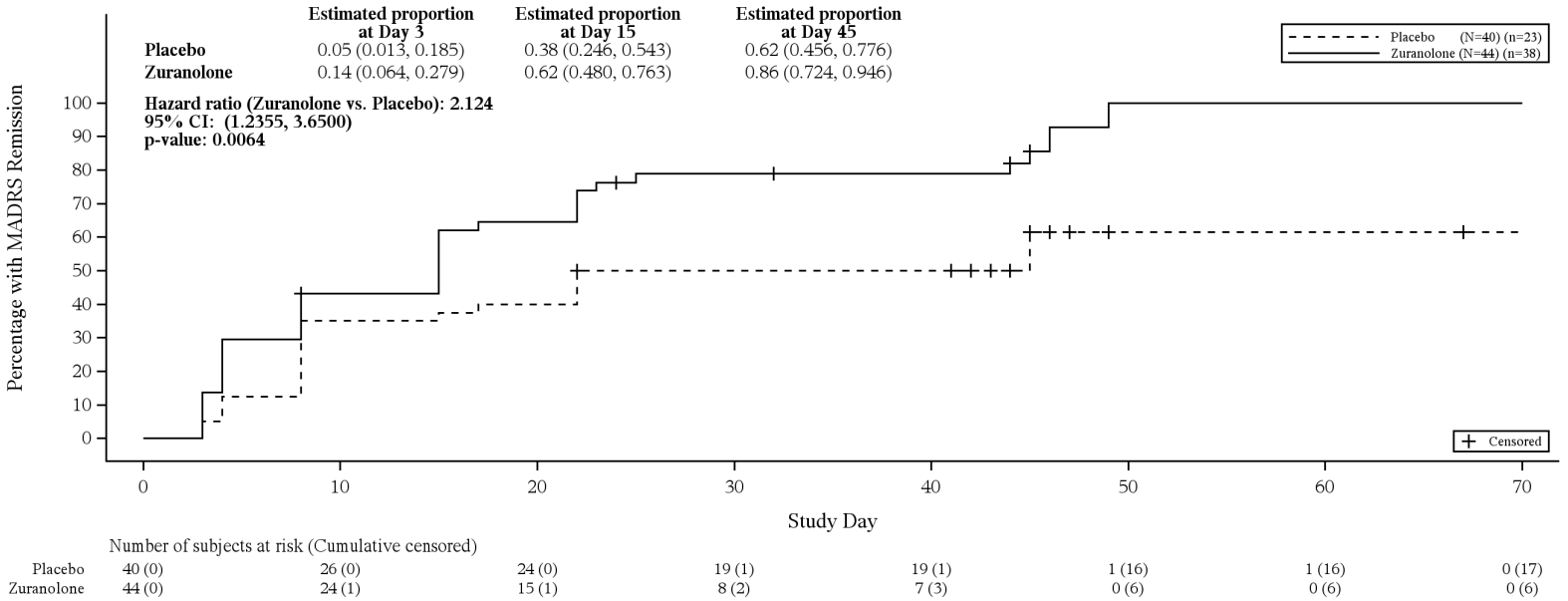
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

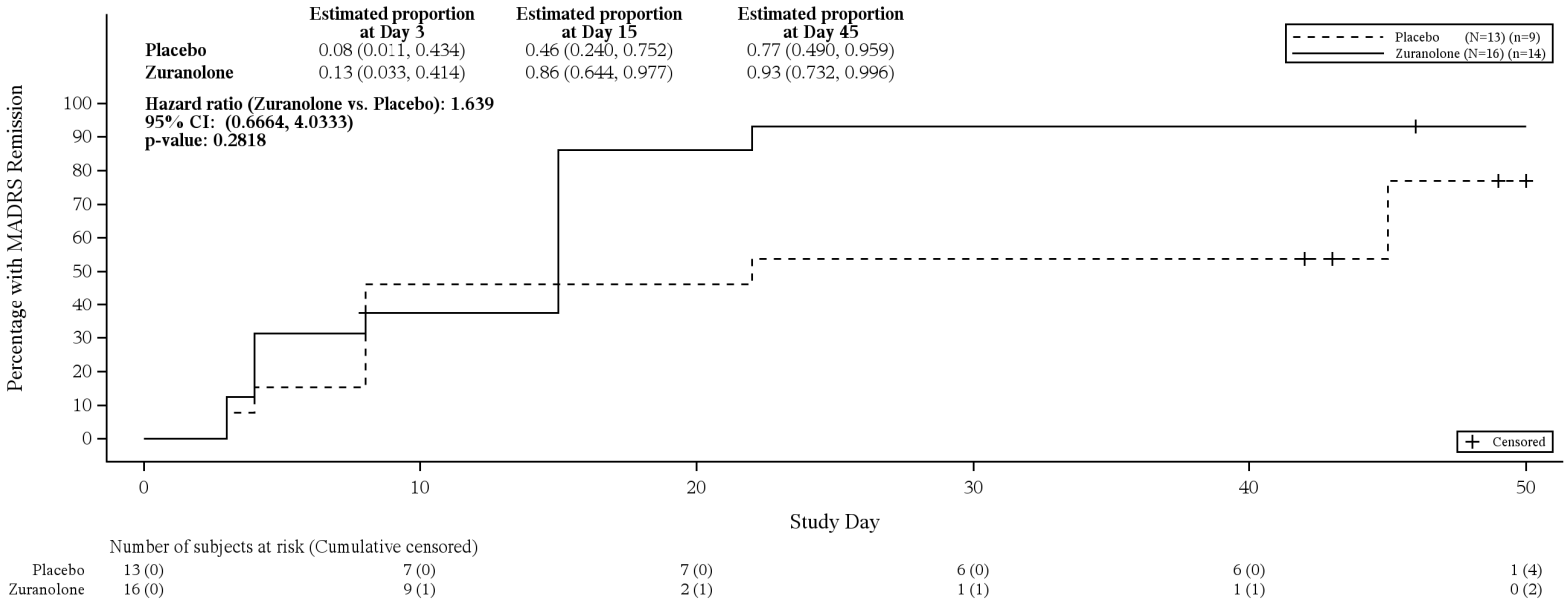
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

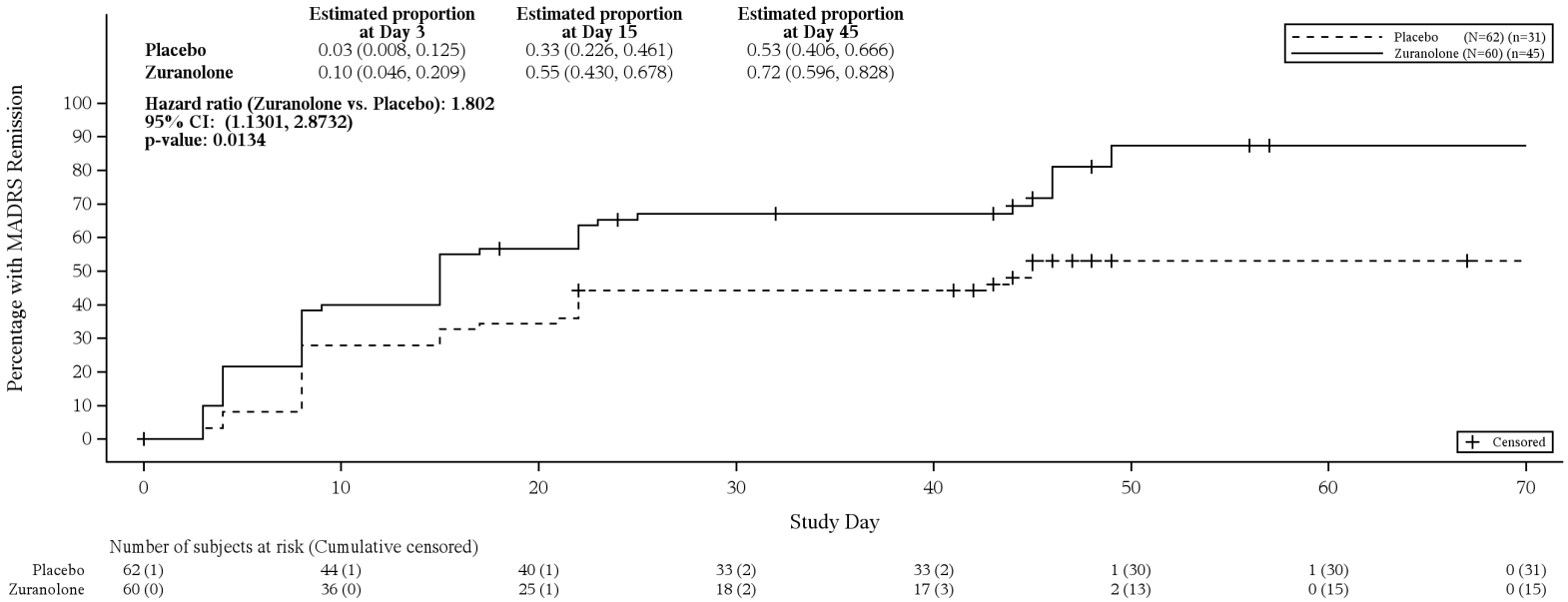
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

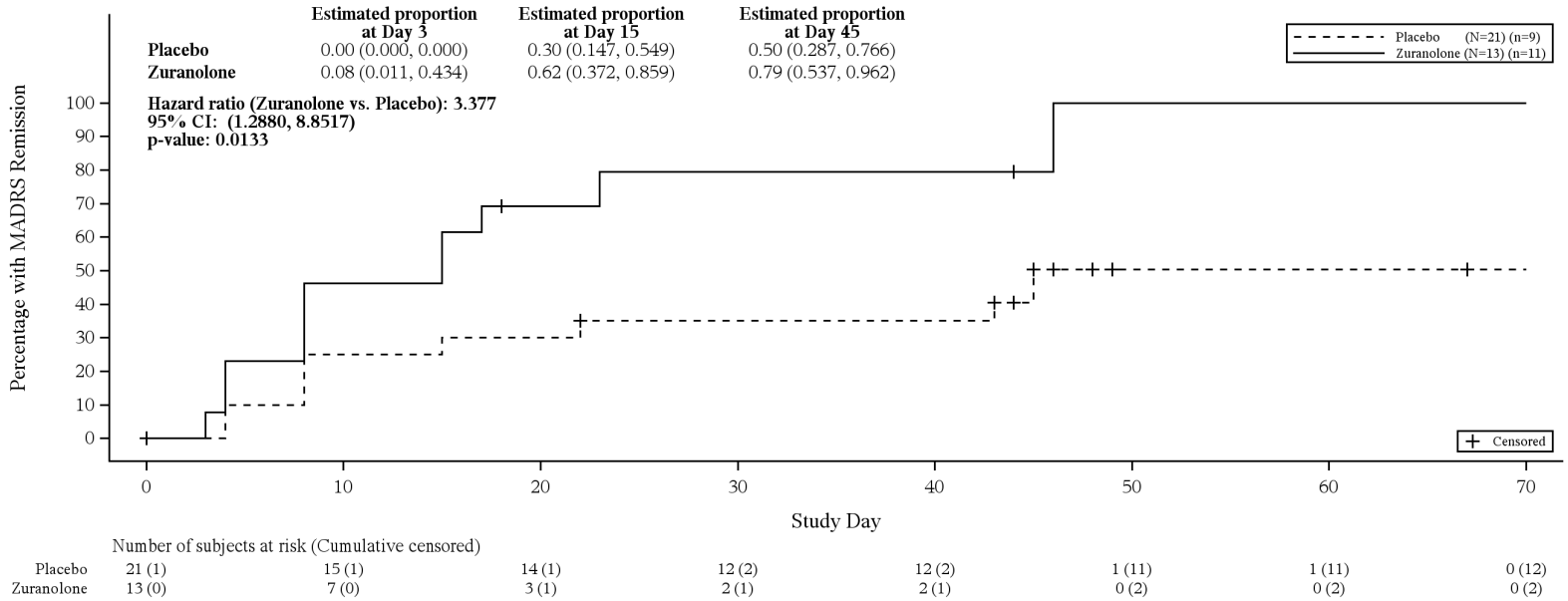
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

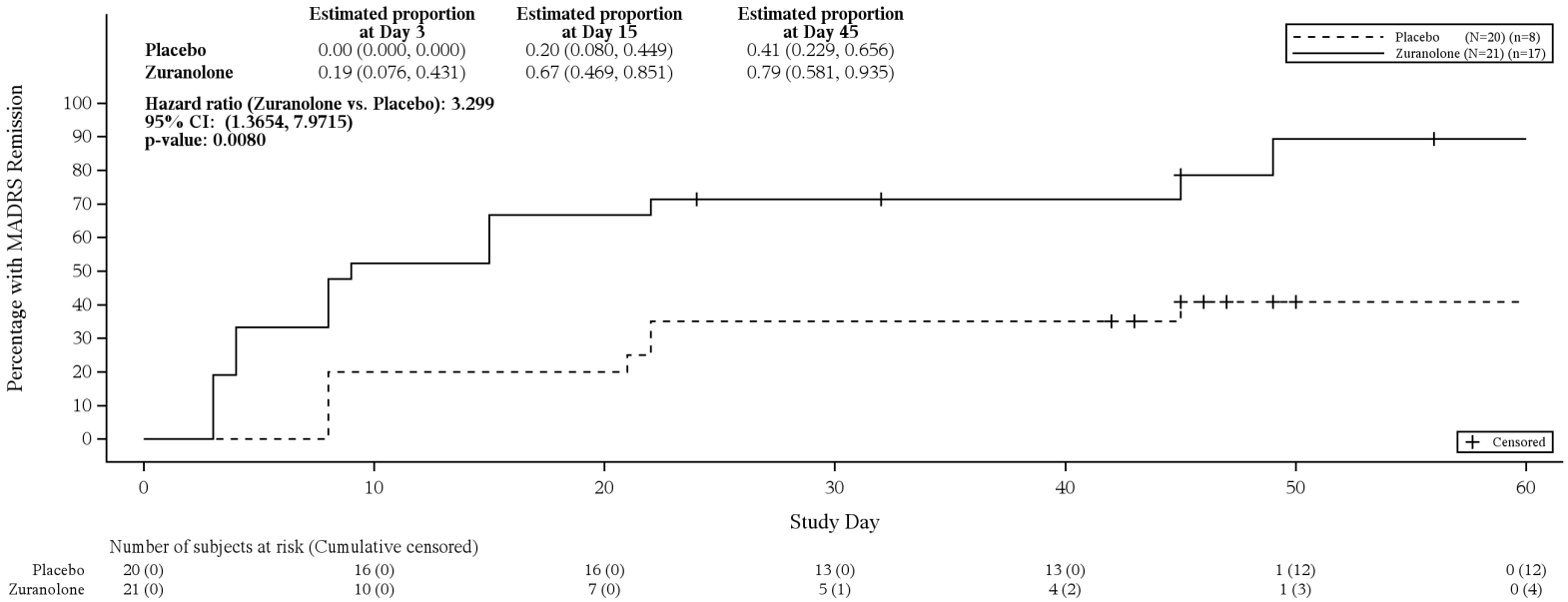
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

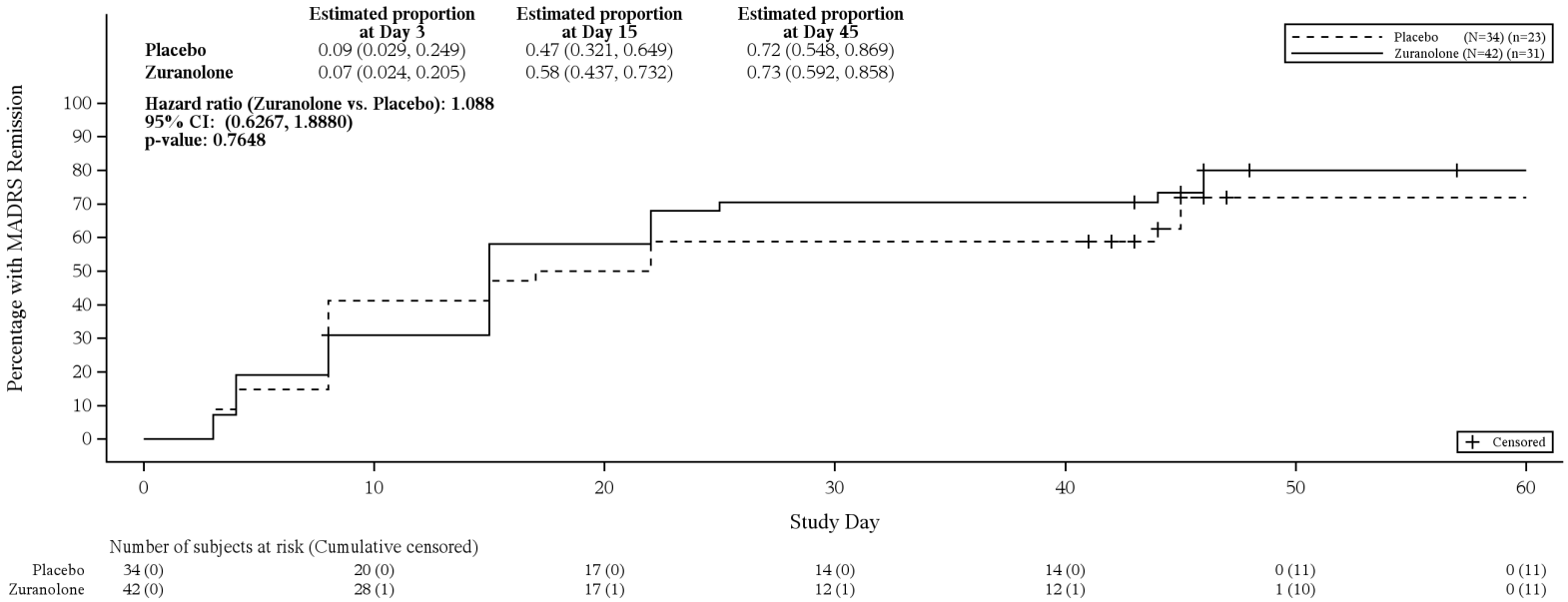
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

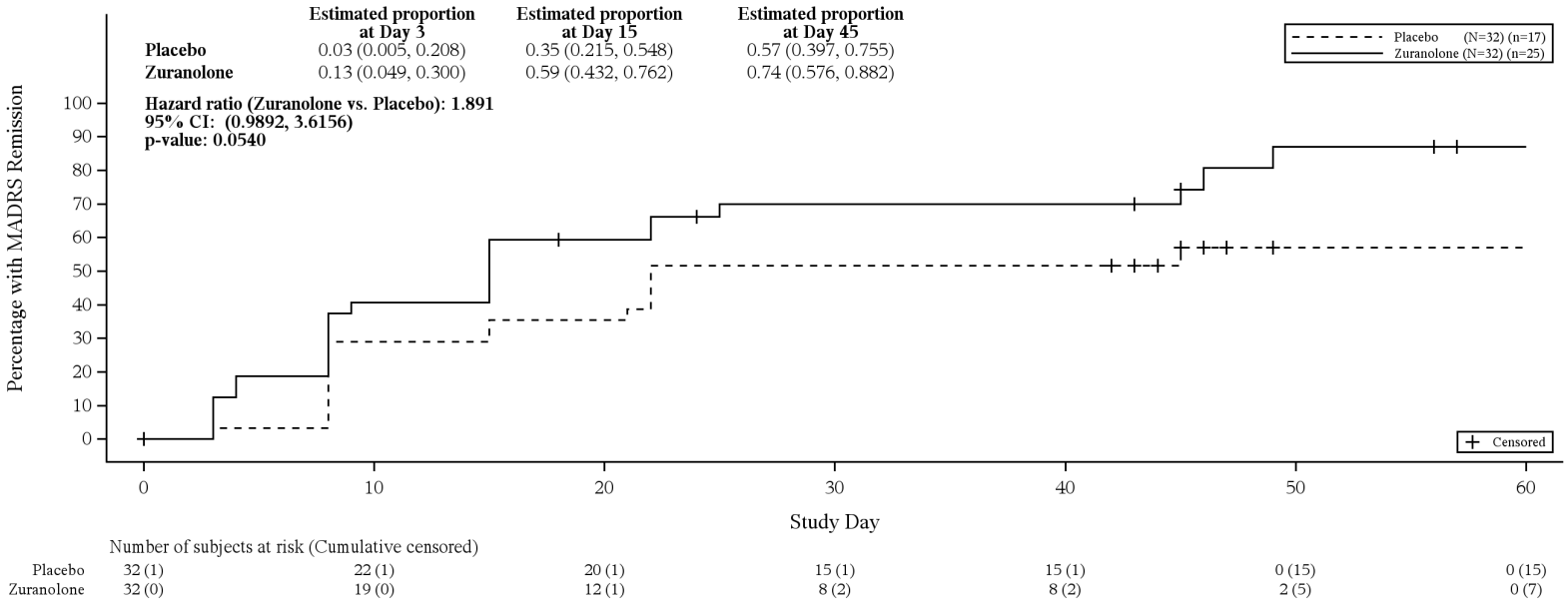
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Number of subjects at risk (Cumulative censored)

Placebo	32 (1)	22 (1)	20 (1)	15 (1)	15 (1)	0 (15)	0 (15)
Zuranolone	32 (0)	19 (0)	12 (1)	8 (2)	8 (2)	2 (5)	0 (7)

Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

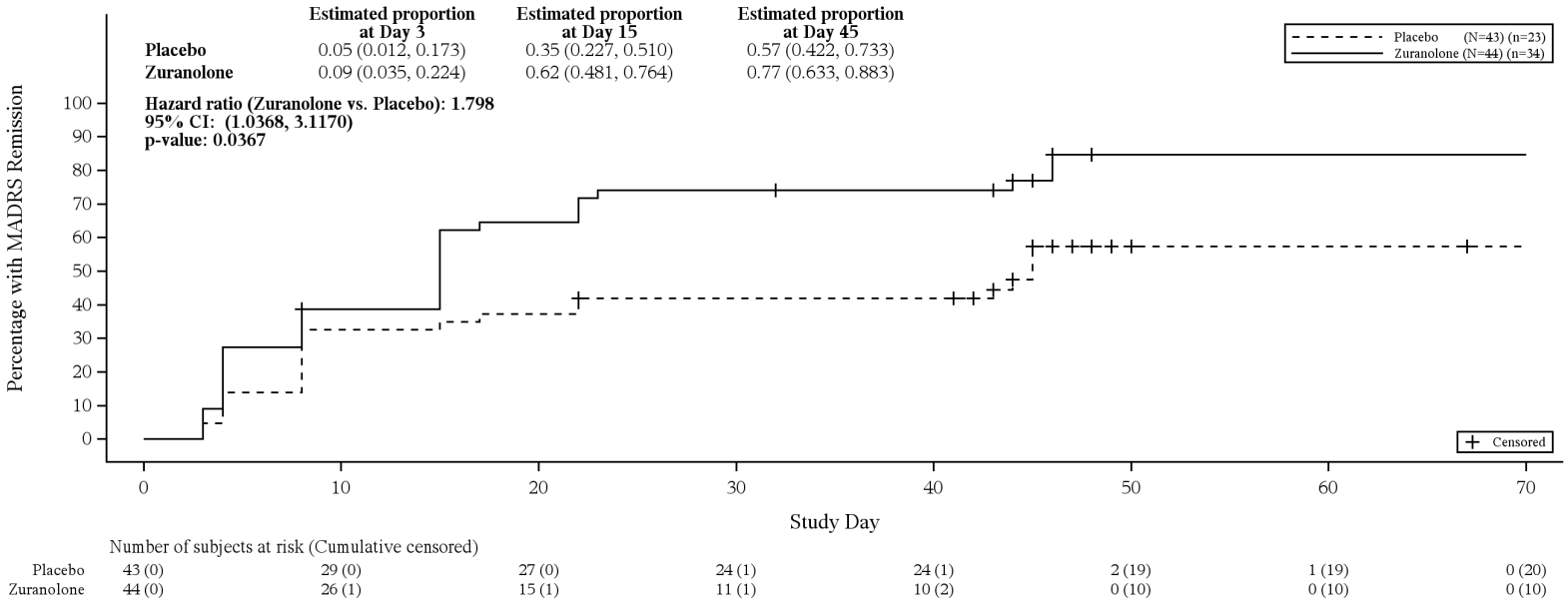
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

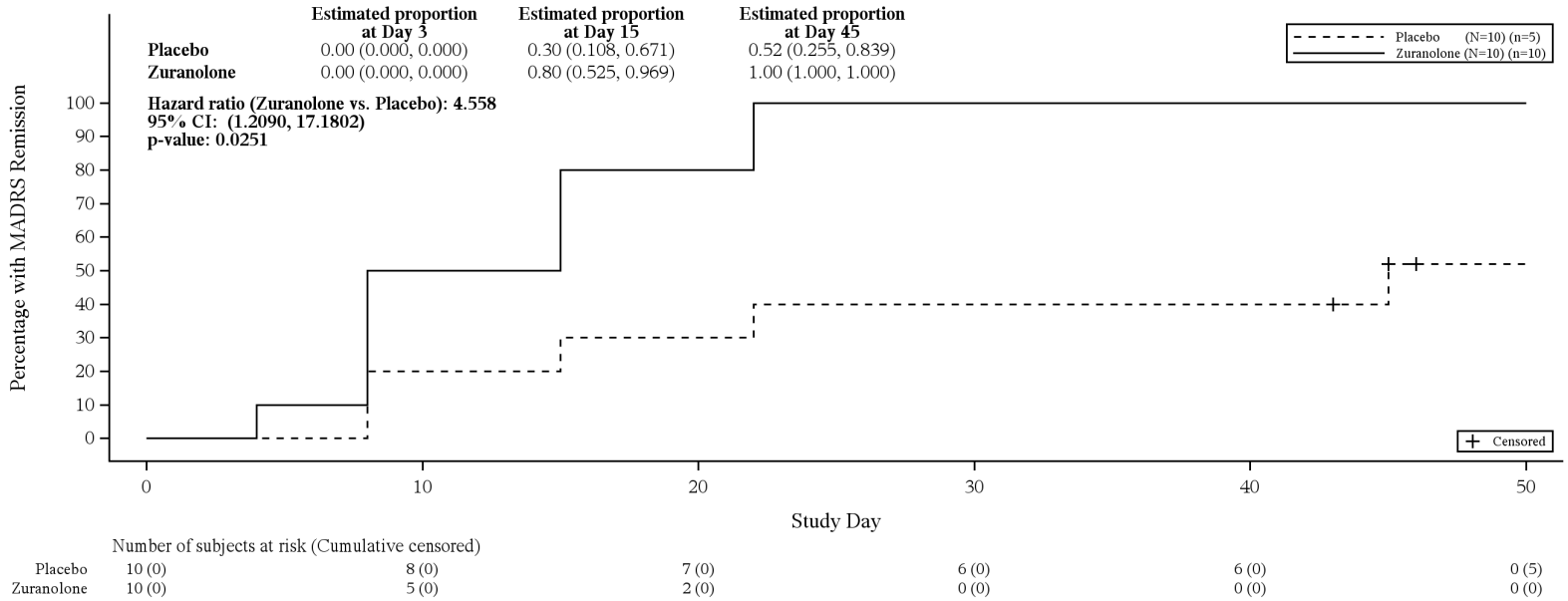
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

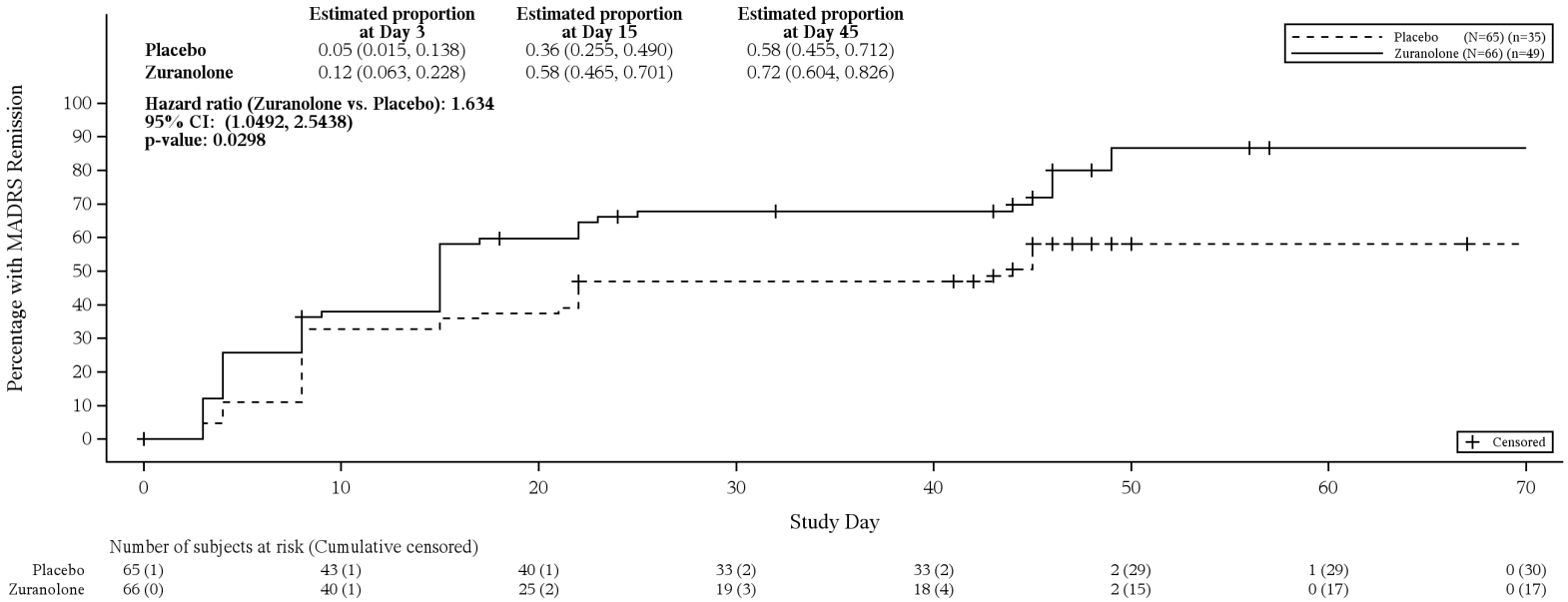
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

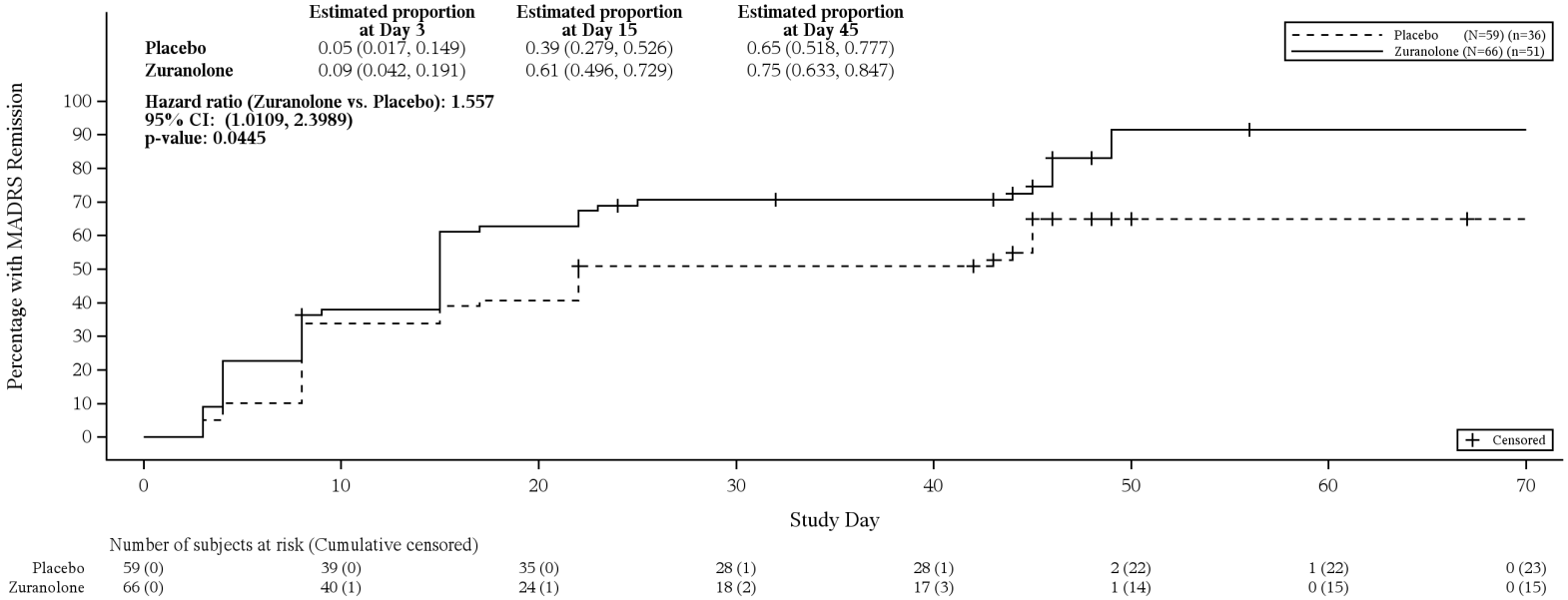
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

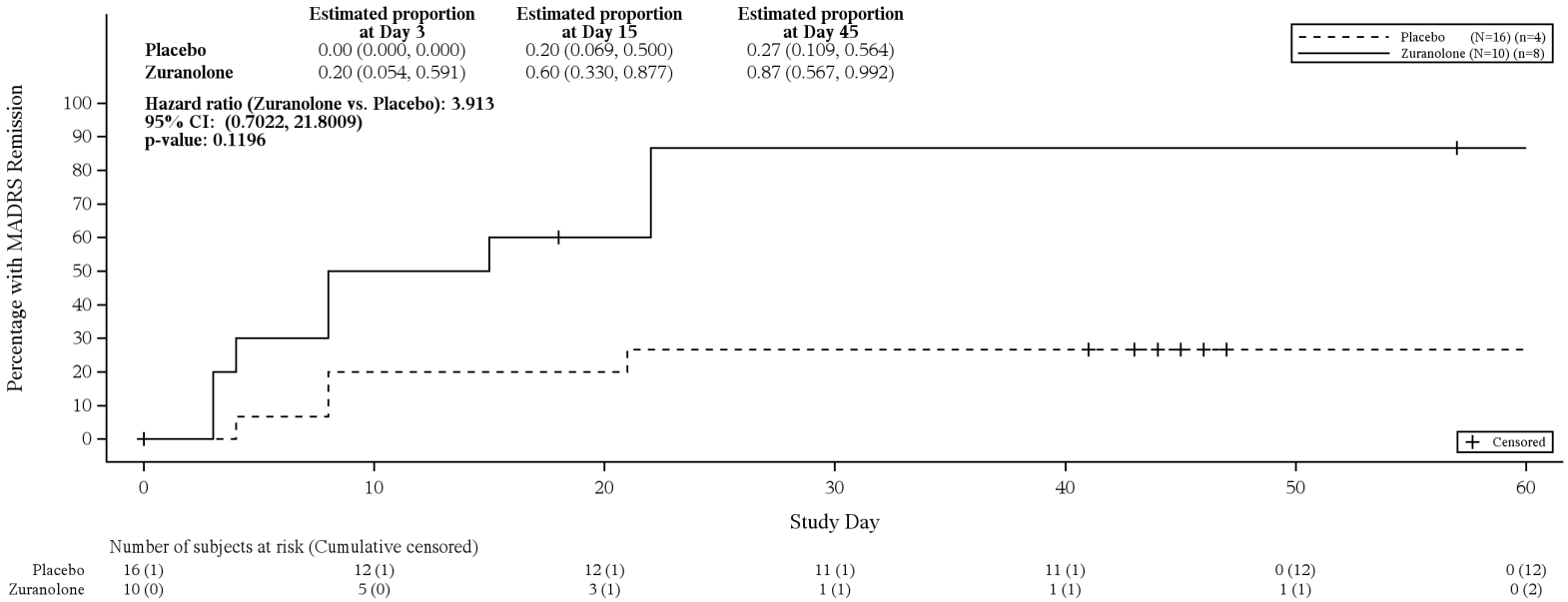
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Number of subjects at risk (Cumulative censored)

Placebo	16 (1)	12 (1)	12 (1)	11 (1)	11 (1)	0 (12)	0 (12)
Zuranolone	10 (0)	5 (0)	3 (1)	1 (1)	1 (1)	1 (1)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with remission.

NOTE 1: Subjects with non-missing MADRS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: MADRS remission is defined as MADRS total score <=10. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-201-by.sas:f-madrs-remi-tte-201-by-itta.rtf **Run Date:** 08JAN2026

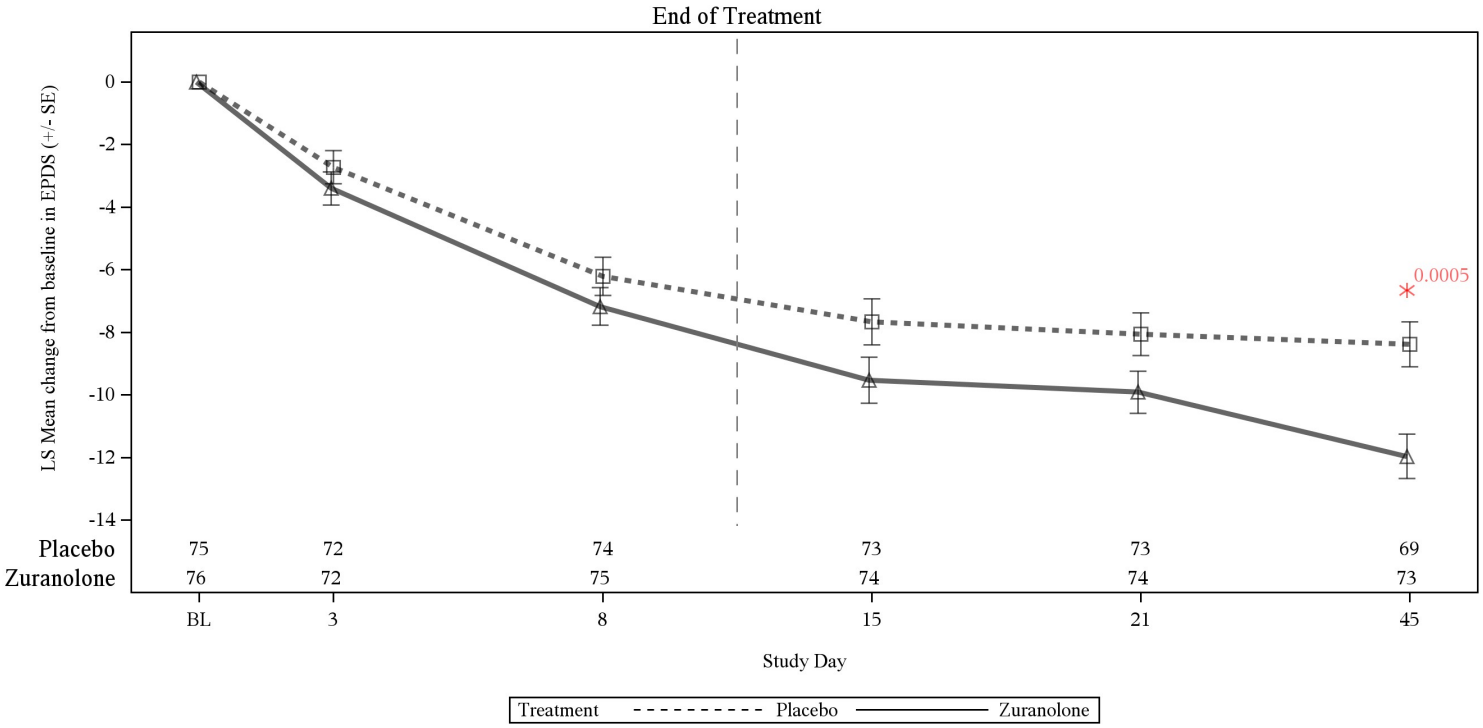
4.3 EPDS

4.3.1 MMRM

4.3.1.1 ITT-Population

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time: 217-PPD-201B - ITT population

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Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-ovr.sas:f-epds-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 3		
n	72	72
LS Mean (SE)	-2.72 (0.533)	-3.40 (0.532)
95% CI for the LS Mean	-3.77, -1.67	-4.45, -2.35
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.68 (0.753)
95% CI for the LS Mean		-2.17, 0.81
p-value		0.3693
Hedges' g (Zuranolone vs. Placebo)		-0.149
95% CI for Hedges' g		-0.4764, 0.1778
Day 8		
n	74	75
LS Mean (SE)	-6.21 (0.609)	-7.17 (0.605)
95% CI for the LS Mean	-7.41, -5.01	-8.37, -5.98
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.96 (0.859)
95% CI for the LS Mean		-2.66, 0.73
p-value		0.2640
Hedges' g (Zuranolone vs. Placebo)		-0.183
95% CI for Hedges' g		-0.5046, 0.1390

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-ovr.sas:t-epds-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	-7.66 (0.735)	-9.53 (0.729)
95% CI for the LS Mean	-9.12, -6.21	-10.97, -8.08
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.86 (1.036)
95% CI for the LS Mean		-3.91, 0.19
p-value		0.0745
Hedges' g (Zuranolone vs. Placebo)		-0.295
95% CI for Hedges' g		-0.6199, 0.0302
Day 21		
n	73	74
LS Mean (SE)	-8.05 (0.682)	-9.91 (0.676)
95% CI for the LS Mean	-9.39, -6.70	-11.25, -8.58
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.87 (0.960)
95% CI for the LS Mean		-3.76, 0.03
p-value		0.0539
Hedges' g (Zuranolone vs. Placebo)		-0.319
95% CI for Hedges' g		-0.6443, 0.0064

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-ovr.sas:t-epds-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 45		
n	69	73
LS Mean (SE)	-8.38 (0.720)	-11.96 (0.705)
95% CI for the LS Mean	-9.80, -6.96	-13.35, -10.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.57 (1.008)
95% CI for the LS Mean		-5.57, -1.58
p-value		0.0005
Hedges' g (Zuranolone vs. Placebo)		-0.592
95% CI for Hedges' g		-0.9283, -0.2558

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-ovr.sas:t-epds-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.3.1.2 Subgruppen

4.3.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.2913
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.3861
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.9199
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.6520
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-int.sas:t-epds-mmrm-201-int-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.8580(a)
25-29.9	20	21	0.4200(b)
>=30	34	42	0.2713(c)
Onset of PPD			
3rd Trimester	32	32	0.3495
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.5223
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.3790
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-int.sas:t-epds-mmrm-201-int-itta.rtf **Run Date:** 29JUL2025

4.3.1.2 .2 Subgruppenanalysen

4.3.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Age Group: 217-PPD-201B - ITT population

Page: 1 of 6

Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Day 3		
n	25	16
LS Mean (SE)	-2.79 (0.990)	-4.01 (1.236)
95% CI for the LS Mean	-4.79, -0.78	-6.51, -1.51
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.22 (1.595)
95% CI for the LS Mean		-4.44, 2.01
p-value		0.4492
Hedges' g (Zuranolone vs. Placebo)		-0.240
95% CI for Hedges' g		-0.8696, 0.3897
Day 8		
n	25	17
LS Mean (SE)	-5.79 (1.066)	-7.88 (1.301)
95% CI for the LS Mean	-7.94, -3.63	-10.51, -5.25
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.10 (1.695)
95% CI for the LS Mean		-5.52, 1.33
p-value		0.2236
Hedges' g (Zuranolone vs. Placebo)		-0.381
95% CI for Hedges' g		-1.0027, 0.2403

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-age-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Age Group: 217-PPD-201B - ITT population

Page: 2 of 6

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	-6.79 (1.282)	-10.82 (1.561)
95% CI for the LS Mean	-9.38, -4.20	-13.98, -7.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.04 (2.030)
95% CI for the LS Mean		-8.14, 0.07
p-value		0.0536
Hedges' g (Zuranolone vs. Placebo)		-0.613
95% CI for Hedges' g		-1.2430, 0.0168
Day 21		
n	25	16
LS Mean (SE)	-7.43 (1.119)	-10.93 (1.380)
95% CI for the LS Mean	-9.69, -5.16	-13.72, -8.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.50 (1.787)
95% CI for the LS Mean		-7.12, 0.11
p-value		0.0571
Hedges' g (Zuranolone vs. Placebo)		-0.615
95% CI for Hedges' g		-1.2569, 0.0261

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-age-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Age Group: 217-PPD-201B - ITT population

Page: 3 of 6

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 45		
n	25	16
LS Mean (SE)	-7.43 (1.197)	-12.79 (1.491)
95% CI for the LS Mean	-9.85, -5.01	-15.81, -9.77
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-5.36 (1.921)
95% CI for the LS Mean		-9.25, -1.48
p-value		0.0081
Hedges' g (Zuranolone vs. Placebo)		-0.876
95% CI for Hedges' g		-1.5316, -0.2206

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-age-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 3		
n	47	56
LS Mean (SE)	-2.61 (0.644)	-3.27 (0.590)
95% CI for the LS Mean	-3.88, -1.33	-4.44, -2.10
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.66 (0.877)
95% CI for the LS Mean		-2.40, 1.08
p-value		0.4522
Hedges' g (Zuranolone vs. Placebo)		-0.148
95% CI for Hedges' g		-0.5364, 0.2401
Day 8		
n	49	58
LS Mean (SE)	-6.37 (0.756)	-7.02 (0.694)
95% CI for the LS Mean	-7.87, -4.87	-8.40, -5.64
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.65 (1.029)
95% CI for the LS Mean		-2.70, 1.39
p-value		0.5264
Hedges' g (Zuranolone vs. Placebo)		-0.122
95% CI for Hedges' g		-0.5031, 0.2582

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-age-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	-8.05 (0.907)	-9.21 (0.831)
95% CI for the LS Mean	-9.85, -6.25	-10.86, -7.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.15 (1.233)
95% CI for the LS Mean		-3.60, 1.29
p-value		0.3516
Hedges' g (Zuranolone vs. Placebo)		-0.182
95% CI for Hedges' g		-0.5667, 0.2028
Day 21		
n	48	58
LS Mean (SE)	-8.31 (0.863)	-9.65 (0.788)
95% CI for the LS Mean	-10.02, -6.60	-11.22, -8.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.35 (1.171)
95% CI for the LS Mean		-3.67, 0.97
p-value		0.2522
Hedges' g (Zuranolone vs. Placebo)		-0.223
95% CI for Hedges' g		-0.6067, 0.1606

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-age-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 45		
n	44	57
LS Mean (SE)	-8.84 (0.910)	-11.75 (0.811)
95% CI for the LS Mean	-10.65, -7.04	-13.36, -10.15
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.91 (1.221)
95% CI for the LS Mean		-5.33, -0.49
p-value		0.0189
Hedges' g (Zuranolone vs. Placebo)		-0.475
95% CI for Hedges' g		-0.8735, -0.0760

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.3.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 3		
n	20	26
LS Mean (SE)	-2.21 (0.860)	-2.54 (0.757)
95% CI for the LS Mean	-3.94, -0.47	-4.07, -1.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.33 (1.148)
95% CI for the LS Mean		-2.65, 1.98
p-value		0.7719
Hedges' g (Zuranolone vs. Placebo)		-0.085
95% CI for Hedges' g		-0.6685, 0.4979
Day 8		
n	22	29
LS Mean (SE)	-6.50 (1.110)	-7.56 (0.965)
95% CI for the LS Mean	-8.73, -4.27	-9.50, -5.62
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.06 (1.472)
95% CI for the LS Mean		-4.02, 1.90
p-value		0.4745
Hedges' g (Zuranolone vs. Placebo)		-0.201
95% CI for Hedges' g		-0.7562, 0.3548

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	-7.96 (1.451)	-8.69 (1.266)
95% CI for the LS Mean	-10.88, -5.04	-11.23, -6.15
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.73 (1.927)
95% CI for the LS Mean		-4.61, 3.14
p-value		0.7056
Hedges' g (Zuranolone vs. Placebo)		-0.107
95% CI for Hedges' g		-0.6654, 0.4522
Day 21		
n	22	28
LS Mean (SE)	-8.00 (1.222)	-8.11 (1.071)
95% CI for the LS Mean	-10.46, -5.55	-10.27, -5.96
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.11 (1.627)
95% CI for the LS Mean		-3.38, 3.16
p-value		0.9463
Hedges' g (Zuranolone vs. Placebo)		-0.019
95% CI for Hedges' g		-0.5774, 0.5394

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 45		
n	22	28
LS Mean (SE)	-9.09 (1.362)	-11.85 (1.203)
95% CI for the LS Mean	-11.84, -6.35	-14.27, -9.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.75 (1.819)
95% CI for the LS Mean		-6.41, 0.91
p-value		0.1367
Hedges' g (Zuranolone vs. Placebo)		-0.425
95% CI for Hedges' g		-0.9892, 0.1399

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 3		
n	52	46
LS Mean (SE)	-2.96 (0.667)	-3.94 (0.710)
95% CI for the LS Mean	-4.29, -1.64	-5.35, -2.53
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.98 (0.975)
95% CI for the LS Mean		-2.92, 0.95
p-value		0.3159
Hedges' g (Zuranolone vs. Placebo)		-0.202
95% CI for Hedges' g		-0.6002, 0.1953
Day 8		
n	52	46
LS Mean (SE)	-6.08 (0.735)	-6.99 (0.782)
95% CI for the LS Mean	-7.54, -4.62	-8.54, -5.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.91 (1.074)
95% CI for the LS Mean		-3.04, 1.22
p-value		0.3983
Hedges' g (Zuranolone vs. Placebo)		-0.170
95% CI for Hedges' g		-0.5678, 0.2270

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	-7.53 (0.846)	-10.05 (0.896)
95% CI for the LS Mean	-9.20, -5.85	-11.83, -8.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.53 (1.233)
95% CI for the LS Mean		-4.97, -0.08
p-value		0.0432
Hedges' g (Zuranolone vs. Placebo)		-0.413
95% CI for Hedges' g		-0.8162, -0.0107
Day 21		
n	51	46
LS Mean (SE)	-8.06 (0.817)	-11.01 (0.865)
95% CI for the LS Mean	-9.69, -6.44	-12.73, -9.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.94 (1.190)
95% CI for the LS Mean		-5.31, -0.58
p-value		0.0151
Hedges' g (Zuranolone vs. Placebo)		-0.499
95% CI for Hedges' g		-0.9038, -0.0944

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 45		
n	47	45
LS Mean (SE)	-8.04 (0.851)	-11.96 (0.883)
95% CI for the LS Mean	-9.73, -6.35	-13.72, -10.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.92 (1.227)
95% CI for the LS Mean		-6.36, -1.49
p-value		0.0019
Hedges' g (Zuranolone vs. Placebo)		-0.661
95% CI for Hedges' g		-1.0808, -0.2413

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.3.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 3		
n	31	29
LS Mean (SE)	-2.63 (0.834)	-3.22 (0.852)
95% CI for the LS Mean	-4.31, -0.96	-4.93, -1.51
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.59 (1.193)
95% CI for the LS Mean		-2.98, 1.80
p-value		0.6241
Hedges' g (Zuranolone vs. Placebo)		-0.126
95% CI for Hedges' g		-0.6325, 0.3811
Day 8		
n	31	31
LS Mean (SE)	-6.09 (1.024)	-7.40 (1.024)
95% CI for the LS Mean	-8.13, -4.04	-9.45, -5.35
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.31 (1.448)
95% CI for the LS Mean		-4.21, 1.59
p-value		0.3686
Hedges' g (Zuranolone vs. Placebo)		-0.227
95% CI for Hedges' g		-0.7267, 0.2722

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-race-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	-7.18 (1.230)	-9.53 (1.230)
95% CI for the LS Mean	-9.64, -4.72	-11.99, -7.07
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.34 (1.740)
95% CI for the LS Mean		-5.83, 1.14
p-value		0.1831
Hedges' g (Zuranolone vs. Placebo)		-0.338
95% CI for Hedges' g		-0.8392, 0.1635
Day 21		
n	31	30
LS Mean (SE)	-7.67 (1.084)	-9.53 (1.092)
95% CI for the LS Mean	-9.84, -5.50	-11.72, -7.34
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.86 (1.539)
95% CI for the LS Mean		-4.94, 1.22
p-value		0.2313
Hedges' g (Zuranolone vs. Placebo)		-0.306
95% CI for Hedges' g		-0.8108, 0.1990

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-race-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Race Group: 217-PPD-201B - ITT population

Page: 3 of 6

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 45		
n	30	30
LS Mean (SE)	-8.05 (1.131)	-11.68 (1.136)
95% CI for the LS Mean	-10.32, -5.79	-13.95, -9.40
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.63 (1.604)
95% CI for the LS Mean		-6.84, -0.42
p-value		0.0275
Hedges' g (Zuranolone vs. Placebo)		-0.576
95% CI for Hedges' g		-1.0927, -0.0598

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-race-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 3		
n	39	42
LS Mean (SE)	-2.75 (0.725)	-3.27 (0.698)
95% CI for the LS Mean	-4.19, -1.31	-4.66, -1.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.52 (1.006)
95% CI for the LS Mean		-2.53, 1.48
p-value		0.6048
Hedges' g (Zuranolone vs. Placebo)		-0.114
95% CI for Hedges' g		-0.5507, 0.3217
Day 8		
n	40	43
LS Mean (SE)	-6.23 (0.790)	-6.92 (0.759)
95% CI for the LS Mean	-7.80, -4.66	-8.44, -5.41
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.69 (1.096)
95% CI for the LS Mean		-2.87, 1.49
p-value		0.5288
Hedges' g (Zuranolone vs. Placebo)		-0.138
95% CI for Hedges' g		-0.5687, 0.2934

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-race-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Race Group: 217-PPD-201B - ITT population

Page: 5 of 6

Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	-7.83 (0.946)	-9.50 (0.909)
95% CI for the LS Mean	-9.72, -5.95	-11.31, -7.69
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.66 (1.312)
95% CI for the LS Mean		-4.28, 0.95
p-value		0.2087
Hedges' g (Zuranolone vs. Placebo)		-0.279
95% CI for Hedges' g		-0.7172, 0.1587
Day 21		
n	39	43
LS Mean (SE)	-8.36 (0.897)	-10.41 (0.858)
95% CI for the LS Mean	-10.14, -6.57	-12.12, -8.70
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.05 (1.242)
95% CI for the LS Mean		-4.52, 0.42
p-value		0.1029
Hedges' g (Zuranolone vs. Placebo)		-0.362
95% CI for Hedges' g		-0.7986, 0.0753

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-race-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 45		
n	36	42
LS Mean (SE)	-8.77 (0.958)	-12.10 (0.901)
95% CI for the LS Mean	-10.68, -6.87	-13.89, -10.30
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.32 (1.315)
95% CI for the LS Mean		-5.94, -0.71
p-value		0.0135
Hedges' g (Zuranolone vs. Placebo)		-0.568
95% CI for Hedges' g		-1.0224, -0.1144

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.3.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 6

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 3		
n	13	14
LS Mean (SE)	-1.32 (1.189)	-3.16 (1.155)
95% CI for the LS Mean	-3.78, 1.14	-5.55, -0.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.84 (1.666)
95% CI for the LS Mean		-5.28, 1.60
p-value		0.2809
Hedges' g (Zuranolone vs. Placebo)		-0.412
95% CI for Hedges' g		-1.1752, 0.3506
Day 8		
n	13	16
LS Mean (SE)	-6.09 (1.534)	-7.66 (1.384)
95% CI for the LS Mean	-9.24, -2.94	-10.50, -4.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.57 (2.072)
95% CI for the LS Mean		-5.82, 2.68
p-value		0.4555
Hedges' g (Zuranolone vs. Placebo)		-0.275
95% CI for Hedges' g		-1.0101, 0.4604

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	-7.32 (1.746)	-11.29 (1.605)
95% CI for the LS Mean	-10.91, -3.74	-14.58, -8.00
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.97 (2.376)
95% CI for the LS Mean		-8.84, 0.91
p-value		0.1065
Hedges' g (Zuranolone vs. Placebo)		-0.614
95% CI for Hedges' g		-1.3744, 0.1455
Day 21		
n	12	15
LS Mean (SE)	-7.63 (1.511)	-9.67 (1.356)
95% CI for the LS Mean	-10.73, -4.53	-12.46, -6.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.04 (2.035)
95% CI for the LS Mean		-6.22, 2.14
p-value		0.3245
Hedges' g (Zuranolone vs. Placebo)		-0.377
95% CI for Hedges' g		-1.1428, 0.3887

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 45		
n	11	15
LS Mean (SE)	-9.76 (1.503)	-11.69 (1.320)
95% CI for the LS Mean	-12.84, -6.68	-14.40, -8.97
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.93 (2.004)
95% CI for the LS Mean		-6.04, 2.19
p-value		0.3448
Hedges' g (Zuranolone vs. Placebo)		-0.370
95% CI for Hedges' g		-1.1543, 0.4147

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 3		
n	59	58
LS Mean (SE)	-3.04 (0.594)	-3.37 (0.599)
95% CI for the LS Mean	-4.22, -1.87	-4.56, -2.18
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.33 (0.844)
95% CI for the LS Mean		-2.00, 1.34
p-value		0.7000
Hedges' g (Zuranolone vs. Placebo)		-0.071
95% CI for Hedges' g		-0.4335, 0.2916
Day 8		
n	61	59
LS Mean (SE)	-6.26 (0.669)	-7.00 (0.679)
95% CI for the LS Mean	-7.58, -4.93	-8.34, -5.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.74 (0.953)
95% CI for the LS Mean		-2.63, 1.14
p-value		0.4375
Hedges' g (Zuranolone vs. Placebo)		-0.141
95% CI for Hedges' g		-0.4997, 0.2170

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	-7.76 (0.810)	-9.03 (0.817)
95% CI for the LS Mean	-9.36, -6.15	-10.65, -7.42
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.28 (1.150)
95% CI for the LS Mean		-3.56, 1.00
p-value		0.2688
Hedges' g (Zuranolone vs. Placebo)		-0.202
95% CI for Hedges' g		-0.5627, 0.1579
Day 21		
n	61	59
LS Mean (SE)	-8.14 (0.769)	-9.95 (0.778)
95% CI for the LS Mean	-9.67, -6.62	-11.49, -8.41
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.80 (1.093)
95% CI for the LS Mean		-3.97, 0.36
p-value		0.1015
Hedges' g (Zuranolone vs. Placebo)		-0.299
95% CI for Hedges' g		-0.6593, 0.0605

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 45		
n	58	58
LS Mean (SE)	-8.14 (0.812)	-12.01 (0.815)
95% CI for the LS Mean	-9.75, -6.53	-13.62, -10.39
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.87 (1.150)
95% CI for the LS Mean		-6.15, -1.59
p-value		0.0010
Hedges' g (Zuranolone vs. Placebo)		-0.620
95% CI for Hedges' g		-0.9929, -0.2477

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.3.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 3		
n	20	13
LS Mean (SE)	-3.18 (1.121)	-2.80 (1.399)
95% CI for the LS Mean	-5.47, -0.89	-5.66, 0.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.38 (1.804)
95% CI for the LS Mean		-3.31, 4.06
p-value		0.8349
Hedges' g (Zuranolone vs. Placebo)		0.073
95% CI for Hedges' g		-0.6254, 0.7716
Day 8		
n	20	13
LS Mean (SE)	-7.23 (1.143)	-6.95 (1.427)
95% CI for the LS Mean	-9.57, -4.89	-9.87, -4.04
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.28 (1.840)
95% CI for the LS Mean		-3.48, 4.03
p-value		0.8820
Hedges' g (Zuranolone vs. Placebo)		0.052
95% CI for Hedges' g		-0.6463, 0.7504

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	-7.83 (1.525)	-10.19 (1.899)
95% CI for the LS Mean	-10.94, -4.72	-14.06, -6.31
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.36 (2.444)
95% CI for the LS Mean		-7.34, 2.63
p-value		0.3426
Hedges' g (Zuranolone vs. Placebo)		-0.335
95% CI for Hedges' g		-1.0379, 0.3679
Day 21		
n	19	12
LS Mean (SE)	-7.72 (1.338)	-11.09 (1.671)
95% CI for the LS Mean	-10.46, -4.98	-14.51, -7.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.37 (2.150)
95% CI for the LS Mean		-7.77, 1.03
p-value		0.1278
Hedges' g (Zuranolone vs. Placebo)		-0.563
95% CI for Hedges' g		-1.2991, 0.1732

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 45		
n	18	12
LS Mean (SE)	-7.48 (1.380)	-13.82 (1.698)
95% CI for the LS Mean	-10.31, -4.66	-17.30, -10.34
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-6.34 (2.199)
95% CI for the LS Mean		-10.84, -1.83
p-value		0.0075
Hedges' g (Zuranolone vs. Placebo)		-1.045
95% CI for Hedges' g		-1.8217, -0.2681

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

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Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 3		
n	19	20
LS Mean (SE)	-1.14 (1.095)	-4.60 (1.072)
95% CI for the LS Mean	-3.36, 1.09	-6.78, -2.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.46 (1.550)
95% CI for the LS Mean		-6.61, -0.32
p-value		0.0320
Hedges' g (Zuranolone vs. Placebo)		-0.701
95% CI for Hedges' g		-1.3480, -0.0543
Day 8		
n	20	20
LS Mean (SE)	-5.34 (1.242)	-8.72 (1.227)
95% CI for the LS Mean	-7.86, -2.82	-11.21, -6.24
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.38 (1.764)
95% CI for the LS Mean		-6.95, 0.19
p-value		0.0628
Hedges' g (Zuranolone vs. Placebo)		-0.594
95% CI for Hedges' g		-1.2275, 0.0392

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	-7.19 (1.497)	-10.59 (1.472)
95% CI for the LS Mean	-10.23, -4.16	-13.57, -7.61
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.40 (2.116)
95% CI for the LS Mean		-7.68, 0.89
p-value		0.1167
Hedges' g (Zuranolone vs. Placebo)		-0.498
95% CI for Hedges' g		-1.1269, 0.1317
Day 21		
n	20	21
LS Mean (SE)	-7.74 (1.486)	-11.13 (1.452)
95% CI for the LS Mean	-10.75, -4.73	-14.07, -8.19
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.39 (2.094)
95% CI for the LS Mean		-7.63, 0.85
p-value		0.1139
Hedges' g (Zuranolone vs. Placebo)		-0.496
95% CI for Hedges' g		-1.1174, 0.1260

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 45		
n	20	20
LS Mean (SE)	-7.99 (1.496)	-12.16 (1.480)
95% CI for the LS Mean	-11.03, -4.96	-15.16, -9.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.17 (2.120)
95% CI for the LS Mean		-8.47, 0.13
p-value		0.0568
Hedges' g (Zuranolone vs. Placebo)		-0.610
95% CI for Hedges' g		-1.2436, 0.0244

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 3		
n	33	39
LS Mean (SE)	-3.22 (0.685)	-3.07 (0.627)
95% CI for the LS Mean	-4.59, -1.86	-4.33, -1.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.15 (0.929)
95% CI for the LS Mean		-1.71, 2.00
p-value		0.8741
Hedges' g (Zuranolone vs. Placebo)		0.037
95% CI for Hedges' g		-0.4264, 0.5008
Day 8		
n	34	42
LS Mean (SE)	-5.95 (0.877)	-6.56 (0.790)
95% CI for the LS Mean	-7.69, -4.20	-8.14, -4.99
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.62 (1.180)
95% CI for the LS Mean		-2.97, 1.73
p-value		0.6015
Hedges' g (Zuranolone vs. Placebo)		-0.120
95% CI for Hedges' g		-0.5723, 0.3328

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	-7.66 (1.071)	-8.91 (0.965)
95% CI for the LS Mean	-9.80, -5.53	-10.83, -6.99
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.25 (1.442)
95% CI for the LS Mean		-4.12, 1.63
p-value		0.3907
Hedges' g (Zuranolone vs. Placebo)		-0.200
95% CI for Hedges' g		-0.6593, 0.2597
Day 21		
n	34	41
LS Mean (SE)	-8.21 (0.978)	-9.01 (0.889)
95% CI for the LS Mean	-10.16, -6.26	-10.78, -7.24
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.80 (1.322)
95% CI for the LS Mean		-3.43, 1.84
p-value		0.5481
Hedges' g (Zuranolone vs. Placebo)		-0.139
95% CI for Hedges' g		-0.5937, 0.3166

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 45		
n	31	41
LS Mean (SE)	-8.88 (1.064)	-11.35 (0.939)
95% CI for the LS Mean	-11.00, -6.76	-13.22, -9.48
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.47 (1.420)
95% CI for the LS Mean		-5.30, 0.36
p-value		0.0864
Hedges' g (Zuranolone vs. Placebo)		-0.409
95% CI for Hedges' g		-0.8805, 0.0620

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.3.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 3		
n	31	32
LS Mean (SE)	-2.94 (0.890)	-5.30 (0.876)
95% CI for the LS Mean	-4.72, -1.16	-7.05, -3.55
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.36 (1.250)
95% CI for the LS Mean		-4.86, 0.14
p-value		0.0639
Hedges' g (Zuranolone vs. Placebo)		-0.470
95% CI for Hedges' g		-0.9705, 0.0308
Day 8		
n	31	32
LS Mean (SE)	-5.94 (1.002)	-7.21 (0.986)
95% CI for the LS Mean	-7.94, -3.94	-9.18, -5.23
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.27 (1.407)
95% CI for the LS Mean		-4.08, 1.55
p-value		0.3717
Hedges' g (Zuranolone vs. Placebo)		-0.224
95% CI for Hedges' g		-0.7195, 0.2714

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	-7.42 (1.117)	-10.08 (1.099)
95% CI for the LS Mean	-9.66, -5.19	-12.28, -7.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.66 (1.569)
95% CI for the LS Mean		-5.80, 0.48
p-value		0.0955
Hedges' g (Zuranolone vs. Placebo)		-0.422
95% CI for Hedges' g		-0.9211, 0.0777
Day 21		
n	30	31
LS Mean (SE)	-8.34 (1.070)	-11.00 (1.053)
95% CI for the LS Mean	-10.48, -6.20	-13.11, -8.89
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.66 (1.502)
95% CI for the LS Mean		-5.67, 0.34
p-value		0.0812
Hedges' g (Zuranolone vs. Placebo)		-0.448
95% CI for Hedges' g		-0.9567, 0.0598

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 45		
n	29	30
LS Mean (SE)	-8.31 (1.156)	-12.70 (1.136)
95% CI for the LS Mean	-10.62, -5.99	-14.97, -10.42
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.39 (1.622)
95% CI for the LS Mean		-7.64, -1.15
p-value		0.0089
Hedges' g (Zuranolone vs. Placebo)		-0.696
95% CI for Hedges' g		-1.2214, -0.1701

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 3		
n	41	40
LS Mean (SE)	-2.47 (0.602)	-1.89 (0.608)
95% CI for the LS Mean	-3.67, -1.28	-3.10, -0.68
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.59 (0.856)
95% CI for the LS Mean		-1.12, 2.29
p-value		0.4946
Hedges' g (Zuranolone vs. Placebo)		0.151
95% CI for Hedges' g		-0.2851, 0.5873
Day 8		
n	43	43
LS Mean (SE)	-6.35 (0.779)	-7.21 (0.778)
95% CI for the LS Mean	-7.90, -4.80	-8.76, -5.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.86 (1.103)
95% CI for the LS Mean		-3.05, 1.34
p-value		0.4398
Hedges' g (Zuranolone vs. Placebo)		-0.166
95% CI for Hedges' g		-0.5893, 0.2575

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	-7.79 (1.025)	-9.15 (1.022)
95% CI for the LS Mean	-9.83, -5.75	-11.19, -7.12
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.37 (1.449)
95% CI for the LS Mean		-4.25, 1.52
p-value		0.3484
Hedges' g (Zuranolone vs. Placebo)		-0.204
95% CI for Hedges' g		-0.6327, 0.2249
Day 21		
n	43	43
LS Mean (SE)	-7.79 (0.909)	-9.14 (0.907)
95% CI for the LS Mean	-9.60, -5.99	-10.94, -7.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.34 (1.285)
95% CI for the LS Mean		-3.90, 1.21
p-value		0.2989
Hedges' g (Zuranolone vs. Placebo)		-0.223
95% CI for Hedges' g		-0.6474, 0.2006

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 45		
n	40	43
LS Mean (SE)	-8.37 (0.943)	-11.49 (0.924)
95% CI for the LS Mean	-10.25, -6.50	-13.33, -9.65
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.12 (1.321)
95% CI for the LS Mean		-5.75, -0.49
p-value		0.0206
Hedges' g (Zuranolone vs. Placebo)		-0.514
95% CI for Hedges' g		-0.9512, -0.0760

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.3.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 3		
n	10	10
LS Mean (SE)	-2.48 (1.356)	-2.79 (1.359)
95% CI for the LS Mean	-5.36, 0.41	-5.68, 0.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.32 (1.958)
95% CI for the LS Mean		-4.47, 3.83
p-value		0.8727
Hedges' g (Zuranolone vs. Placebo)		-0.070
95% CI for Hedges' g		-0.9465, 0.8070
Day 8		
n	10	10
LS Mean (SE)	-5.58 (1.268)	-6.09 (1.271)
95% CI for the LS Mean	-8.27, -2.88	-8.80, -3.39
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.52 (1.836)
95% CI for the LS Mean		-4.41, 3.38
p-value		0.7811
Hedges' g (Zuranolone vs. Placebo)		-0.121
95% CI for Hedges' g		-0.9984, 0.7563

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	-8.18 (1.739)	-8.29 (1.741)
95% CI for the LS Mean	-11.84, -4.51	-11.96, -4.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.12 (2.490)
95% CI for the LS Mean		-5.35, 5.12
p-value		0.9625
Hedges' g (Zuranolone vs. Placebo)		-0.020
95% CI for Hedges' g		-0.8970, 0.8561
Day 21		
n	10	10
LS Mean (SE)	-7.88 (1.857)	-9.19 (1.859)
95% CI for the LS Mean	-11.78, -3.97	-13.11, -5.28
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.32 (2.655)
95% CI for the LS Mean		-6.90, 4.26
p-value		0.6254
Hedges' g (Zuranolone vs. Placebo)		-0.213
95% CI for Hedges' g		-1.0918, 0.6662

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 45		
n	9	10
LS Mean (SE)	-11.14 (1.494)	-8.99 (1.413)
95% CI for the LS Mean	-14.30, -7.98	-12.00, -5.99
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.14 (2.100)
95% CI for the LS Mean		-2.29, 6.58
p-value		0.3218
Hedges' g (Zuranolone vs. Placebo)		0.448
95% CI for Hedges' g		-0.4635, 1.3600

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 3		
n	62	62
LS Mean (SE)	-2.81 (0.593)	-3.47 (0.591)
95% CI for the LS Mean	-3.98, -1.63	-4.64, -2.30
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.66 (0.837)
95% CI for the LS Mean		-2.32, 0.99
p-value		0.4290
Hedges' g (Zuranolone vs. Placebo)		-0.142
95% CI for Hedges' g		-0.4941, 0.2108
Day 8		
n	64	65
LS Mean (SE)	-6.35 (0.675)	-7.29 (0.668)
95% CI for the LS Mean	-7.69, -5.02	-8.61, -5.97
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.94 (0.949)
95% CI for the LS Mean		-2.81, 0.94
p-value		0.3265
Hedges' g (Zuranolone vs. Placebo)		-0.172
95% CI for Hedges' g		-0.5182, 0.1734

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	-7.63 (0.810)	-9.67 (0.802)
95% CI for the LS Mean	-9.23, -6.02	-11.25, -8.08
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.04 (1.140)
95% CI for the LS Mean		-4.30, 0.21
p-value		0.0756
Hedges' g (Zuranolone vs. Placebo)		-0.316
95% CI for Hedges' g		-0.6660, 0.0340
Day 21		
n	63	64
LS Mean (SE)	-8.11 (0.743)	-9.96 (0.736)
95% CI for the LS Mean	-9.58, -6.64	-11.42, -8.51
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.85 (1.045)
95% CI for the LS Mean		-3.92, 0.22
p-value		0.0793
Hedges' g (Zuranolone vs. Placebo)		-0.312
95% CI for Hedges' g		-0.6620, 0.0379

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 45		
n	60	63
LS Mean (SE)	-8.05 (0.795)	-12.37 (0.780)
95% CI for the LS Mean	-9.62, -6.48	-13.91, -10.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.32 (1.114)
95% CI for the LS Mean		-6.52, -2.12
p-value		0.0002
Hedges' g (Zuranolone vs. Placebo)		-0.695
95% CI for Hedges' g		-1.0595, -0.3314

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.3.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 3		
n	58	62
LS Mean (SE)	-2.98 (0.592)	-3.38 (0.569)
95% CI for the LS Mean	-4.15, -1.81	-4.51, -2.25
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.40 (0.822)
95% CI for the LS Mean		-2.03, 1.23
p-value		0.6255
Hedges' g (Zuranolone vs. Placebo)		-0.089
95% CI for Hedges' g		-0.4470, 0.2694
Day 8		
n	59	65
LS Mean (SE)	-6.49 (0.706)	-7.21 (0.672)
95% CI for the LS Mean	-7.88, -5.09	-8.54, -5.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.73 (0.974)
95% CI for the LS Mean		-2.66, 1.20
p-value		0.4570
Hedges' g (Zuranolone vs. Placebo)		-0.133
95% CI for Hedges' g		-0.4862, 0.2195

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	-7.99 (0.833)	-9.65 (0.793)
95% CI for the LS Mean	-9.64, -6.35	-11.22, -8.08
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.65 (1.150)
95% CI for the LS Mean		-3.93, 0.62
p-value		0.1531
Hedges' g (Zuranolone vs. Placebo)		-0.258
95% CI for Hedges' g		-0.6131, 0.0973
Day 21		
n	58	65
LS Mean (SE)	-8.38 (0.774)	-9.84 (0.733)
95% CI for the LS Mean	-9.91, -6.85	-11.29, -8.39
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.46 (1.066)
95% CI for the LS Mean		-3.58, 0.65
p-value		0.1721
Hedges' g (Zuranolone vs. Placebo)		-0.247
95% CI for Hedges' g		-0.6019, 0.1088

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 45		
n	55	64
LS Mean (SE)	-8.88 (0.812)	-12.07 (0.760)
95% CI for the LS Mean	-10.49, -7.27	-13.57, -10.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.19 (1.112)
95% CI for the LS Mean		-5.39, -0.98
p-value		0.0049
Hedges' g (Zuranolone vs. Placebo)		-0.523
95% CI for Hedges' g		-0.8899, -0.1570

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 3		
n	14	10
LS Mean (SE)	-1.70 (1.319)	-3.61 (1.566)
95% CI for the LS Mean	-4.44, 1.04	-6.87, -0.35
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.90 (2.073)
95% CI for the LS Mean		-6.21, 2.40
p-value		0.3685
Hedges' g (Zuranolone vs. Placebo)		-0.367
95% CI for Hedges' g		-1.1854, 0.4508
Day 8		
n	15	10
LS Mean (SE)	-5.16 (1.065)	-6.91 (1.304)
95% CI for the LS Mean	-7.37, -2.94	-9.62, -4.19
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.75 (1.719)
95% CI for the LS Mean		-5.32, 1.83
p-value		0.3204
Hedges' g (Zuranolone vs. Placebo)		-0.402
95% CI for Hedges' g		-1.2097, 0.4061

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by History of PPD: 217-PPD-201B - ITT population

Page: 5 of 6

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	-6.41 (1.568)	-8.71 (1.891)
95% CI for the LS Mean	-9.65, -3.17	-12.62, -4.79
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.29 (2.481)
95% CI for the LS Mean		-7.42, 2.83
p-value		0.3647
Hedges' g (Zuranolone vs. Placebo)		-0.370
95% CI for Hedges' g		-1.1878, 0.4486
Day 21		
n	15	9
LS Mean (SE)	-6.76 (1.355)	-10.60 (1.718)
95% CI for the LS Mean	-9.57, -3.94	-14.15, -7.04
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.84 (2.218)
95% CI for the LS Mean		-8.43, 0.75
p-value		0.0967
Hedges' g (Zuranolone vs. Placebo)		-0.705
95% CI for Hedges' g		-1.5551, 0.1451

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by History of PPD: 217-PPD-201B - ITT population

Page: 6 of 6

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 45		
n	14	9
LS Mean (SE)	-6.28 (1.542)	-11.27 (1.933)
95% CI for the LS Mean	-9.47, -3.09	-15.26, -7.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.98 (2.502)
95% CI for the LS Mean		-10.15, 0.18
p-value		0.0580
Hedges' g (Zuranolone vs. Placebo)		-0.820
95% CI for Hedges' g		-1.6905, 0.0500

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

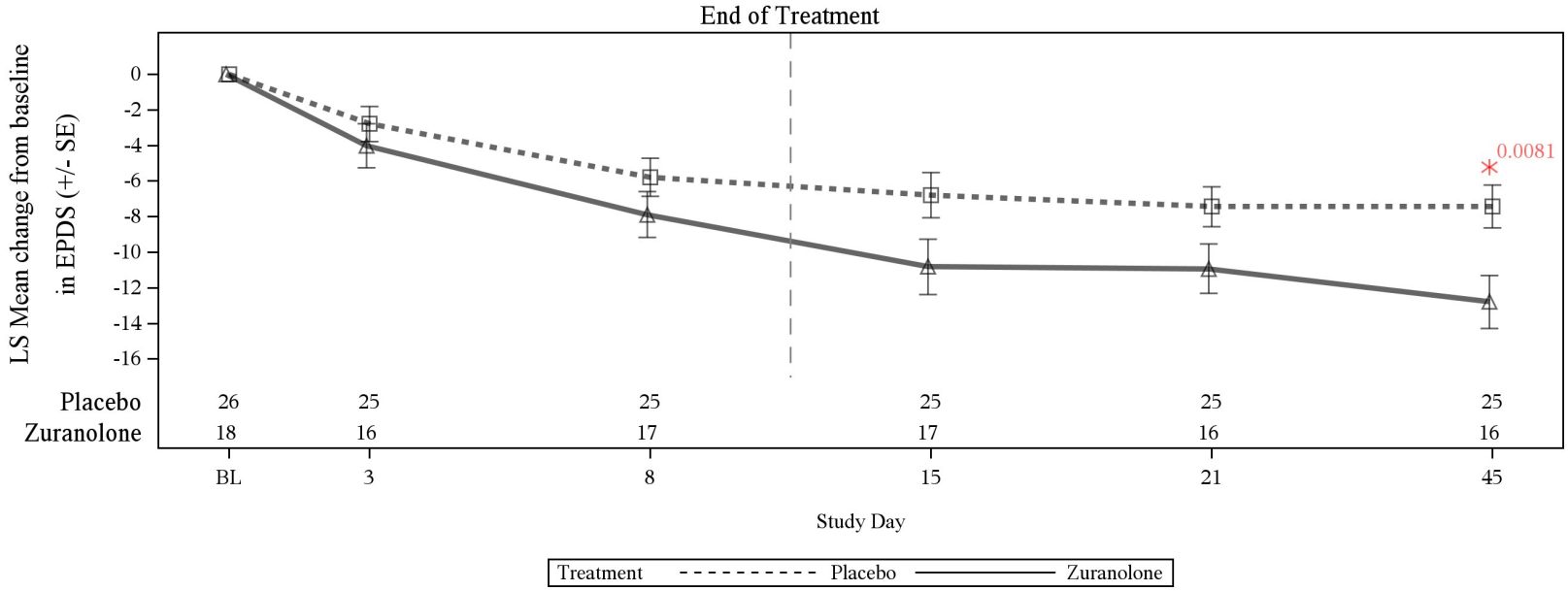
Source: biib125/v_a/germany_amnog/t-epds-mmrm-201-by.sas:t-epds-mmrm-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.3.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

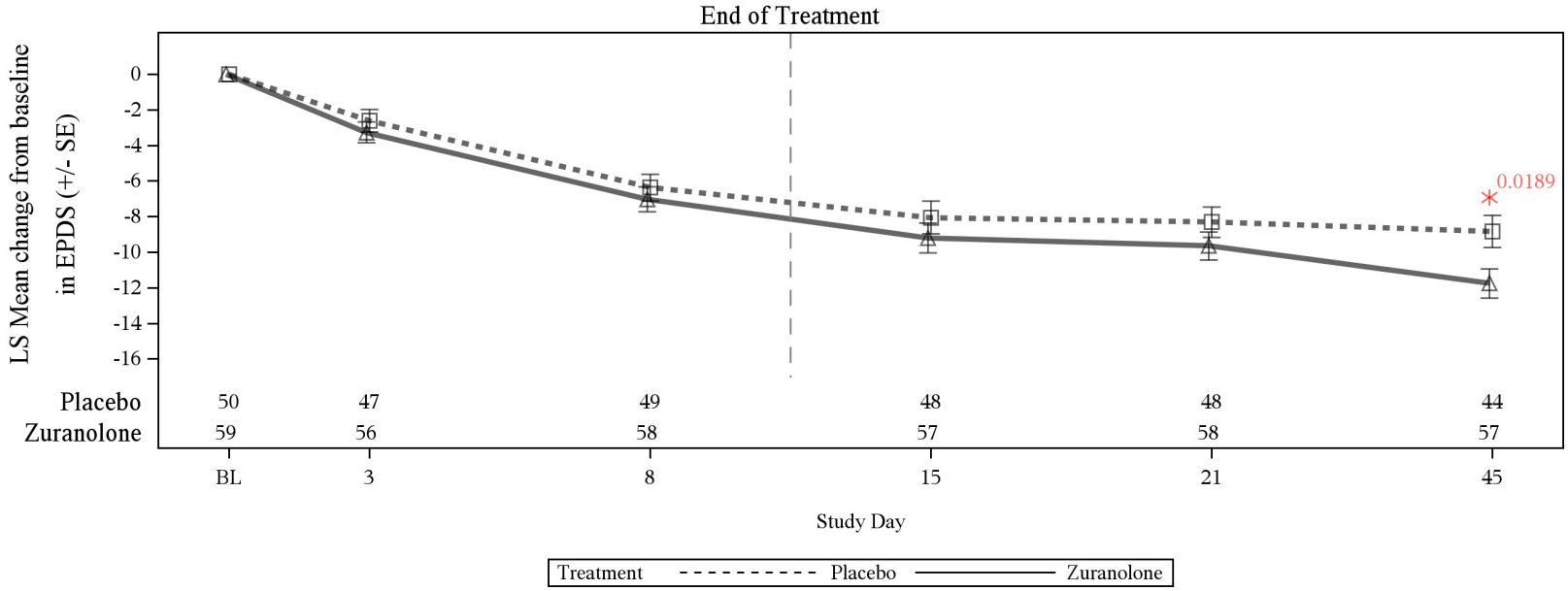
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

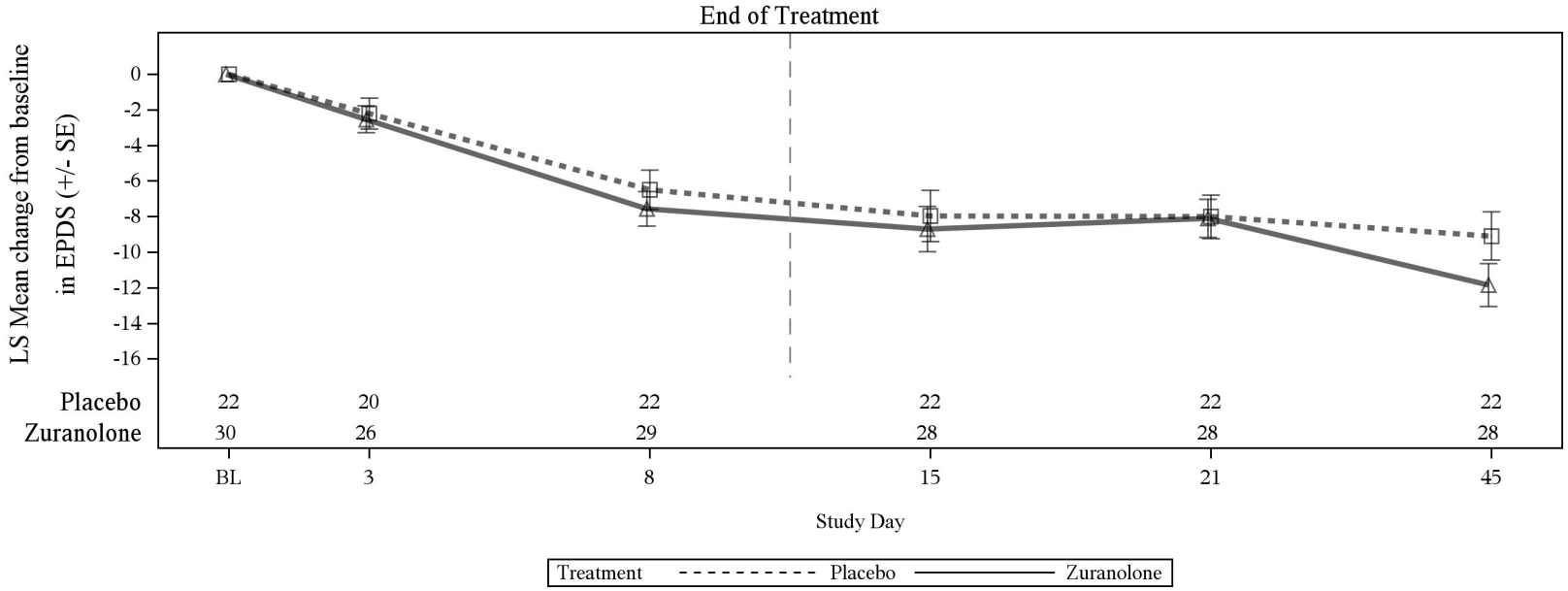
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

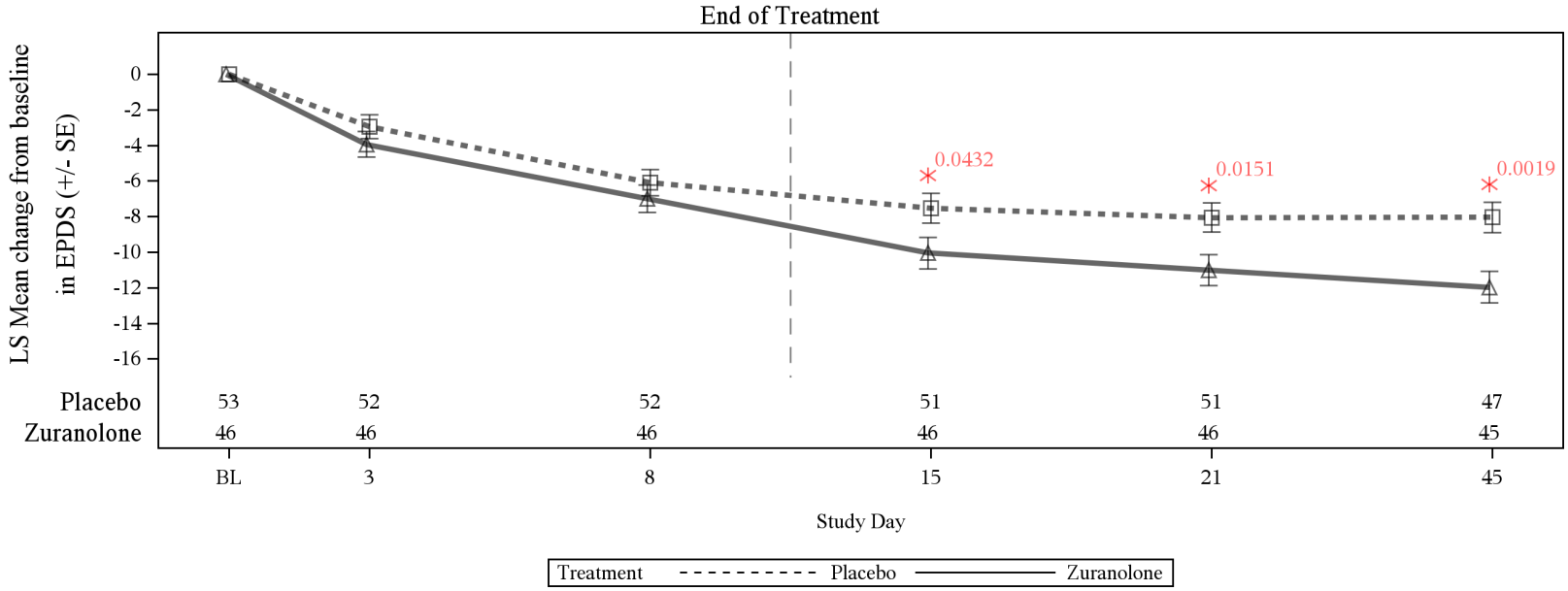
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

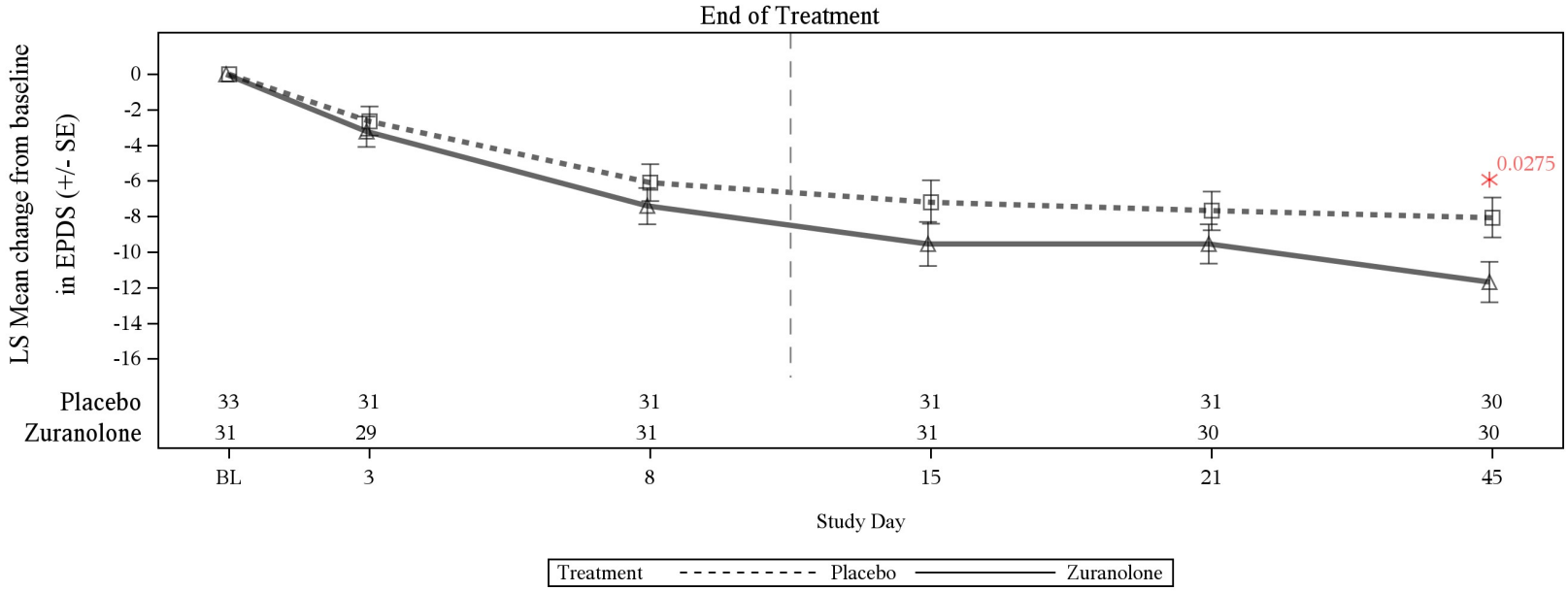
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

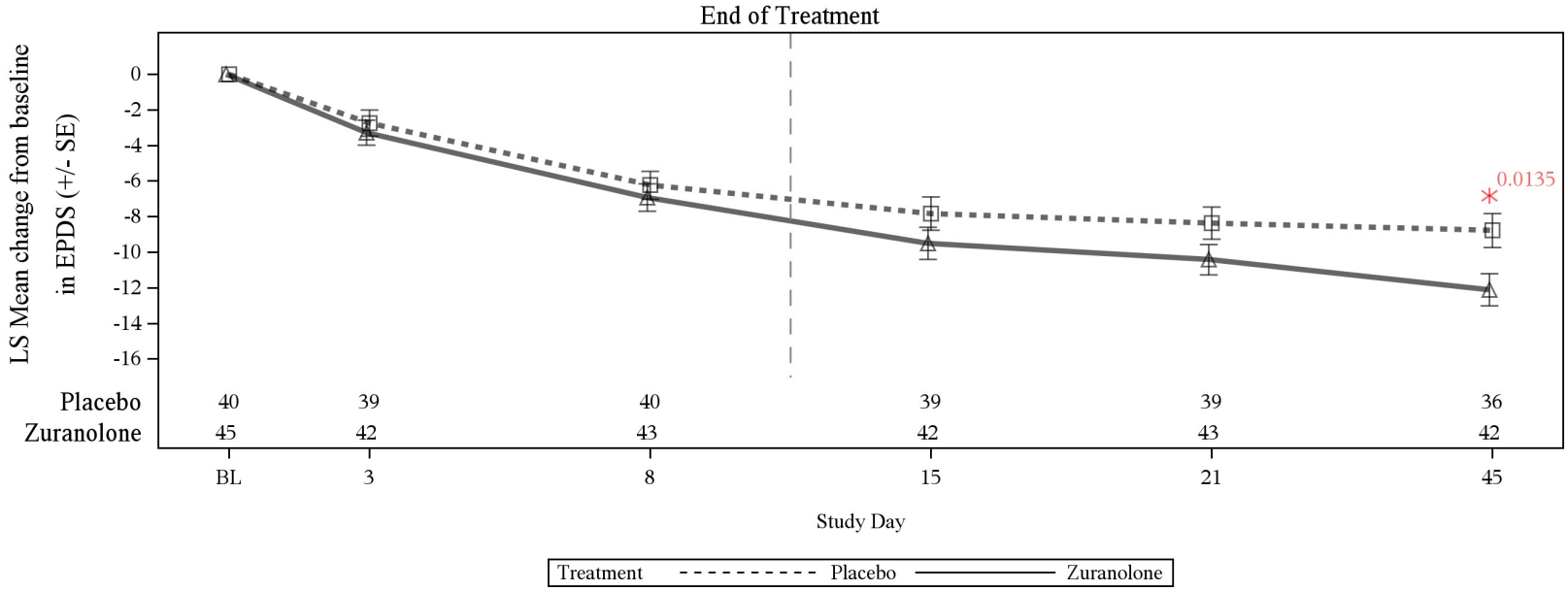
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

Page: 6 of 17

Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

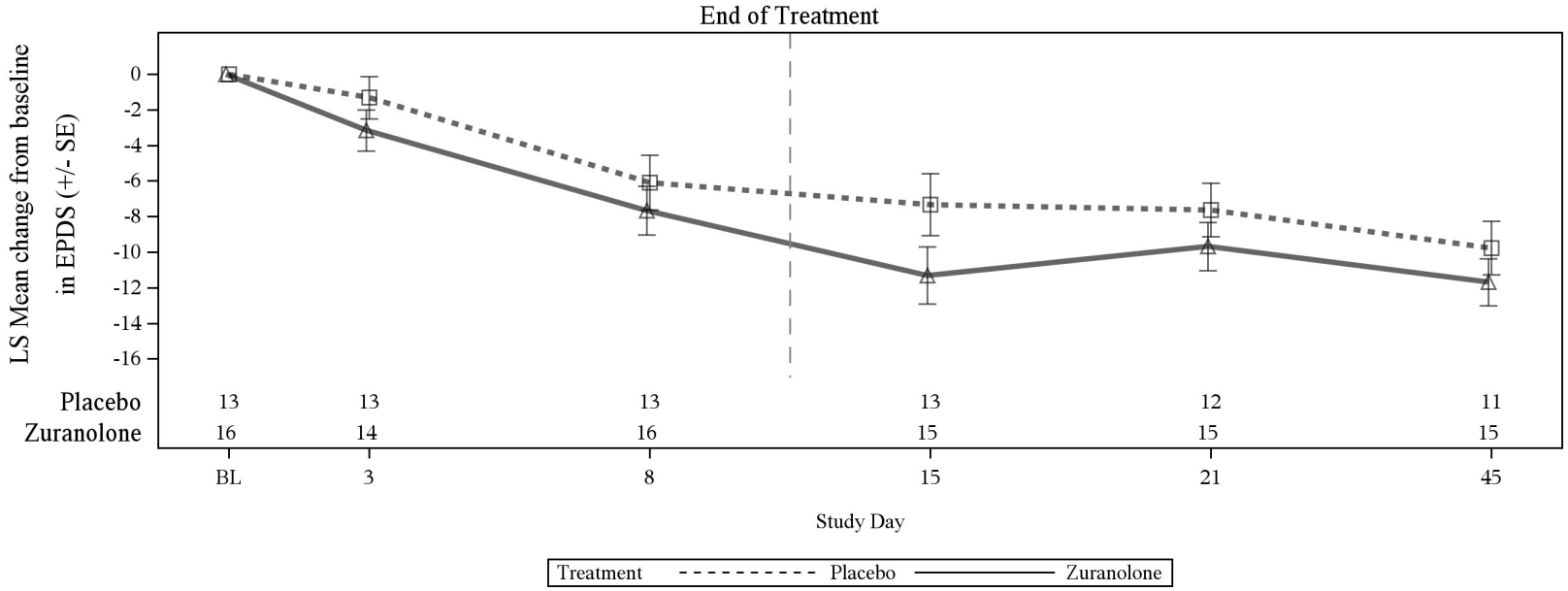
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

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Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

Page: 7 of 17

Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

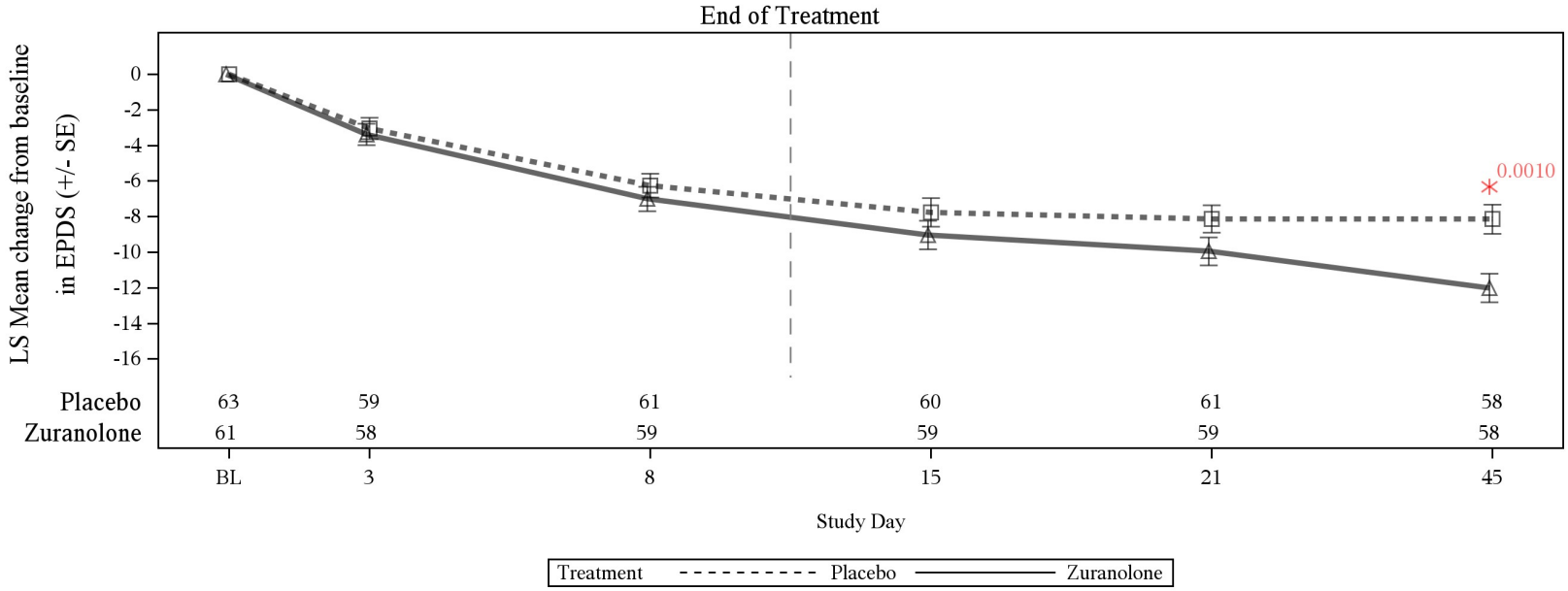
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

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Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

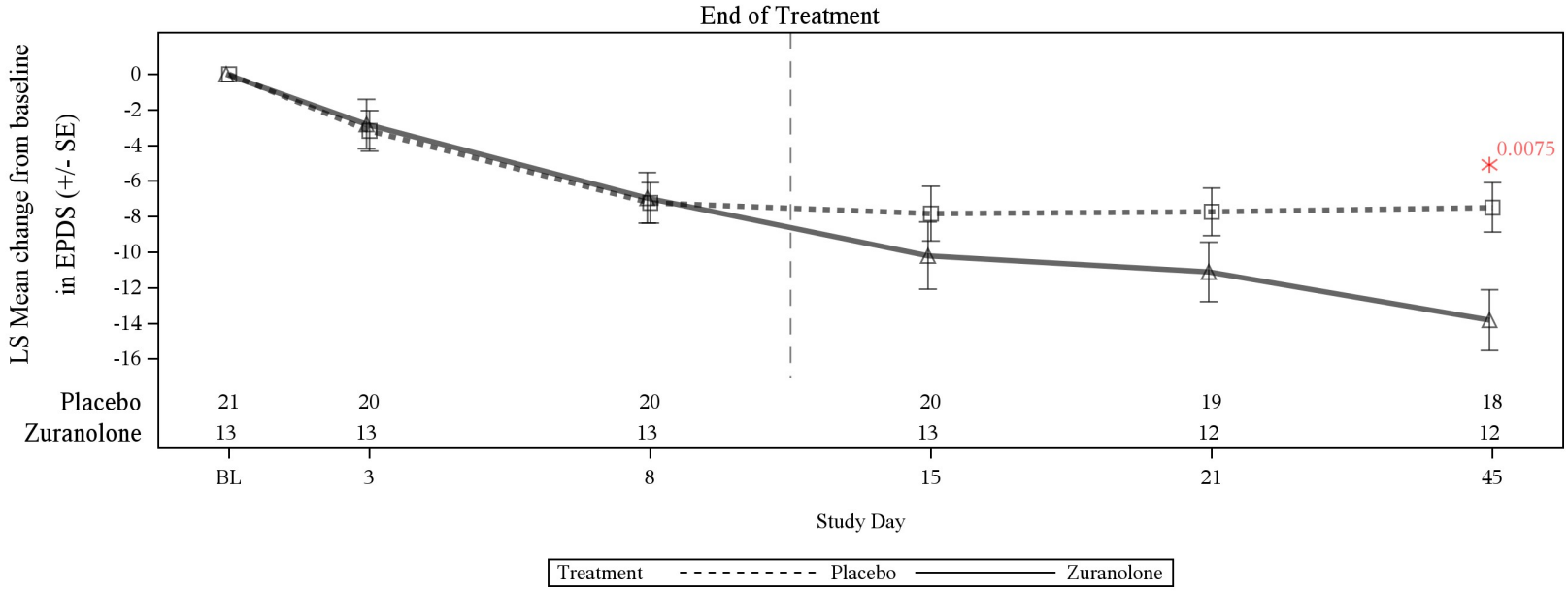
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

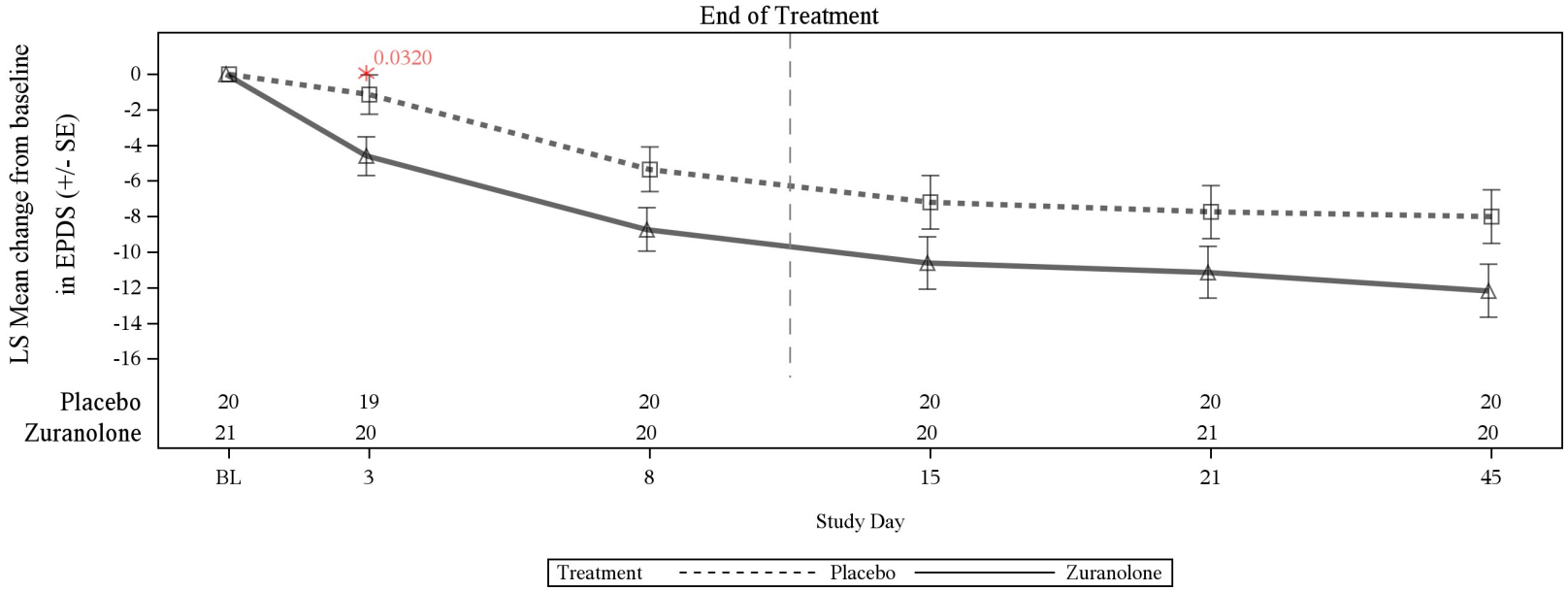
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

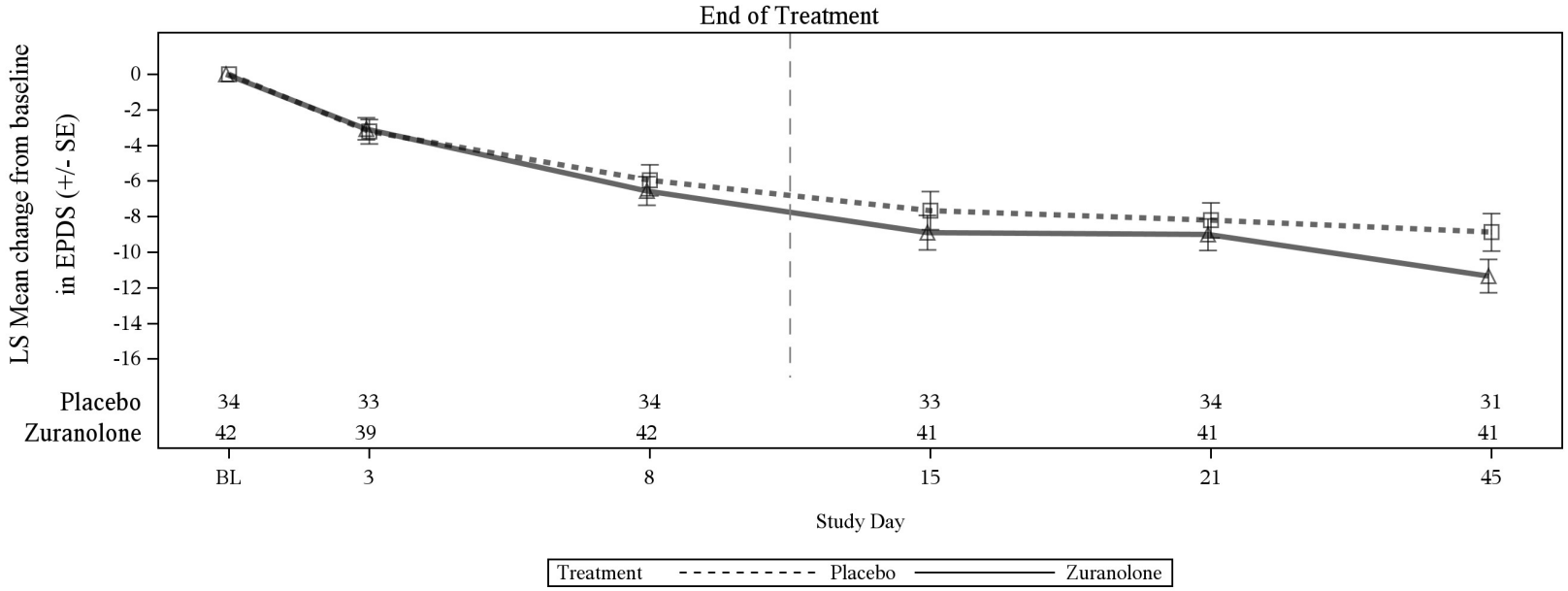
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

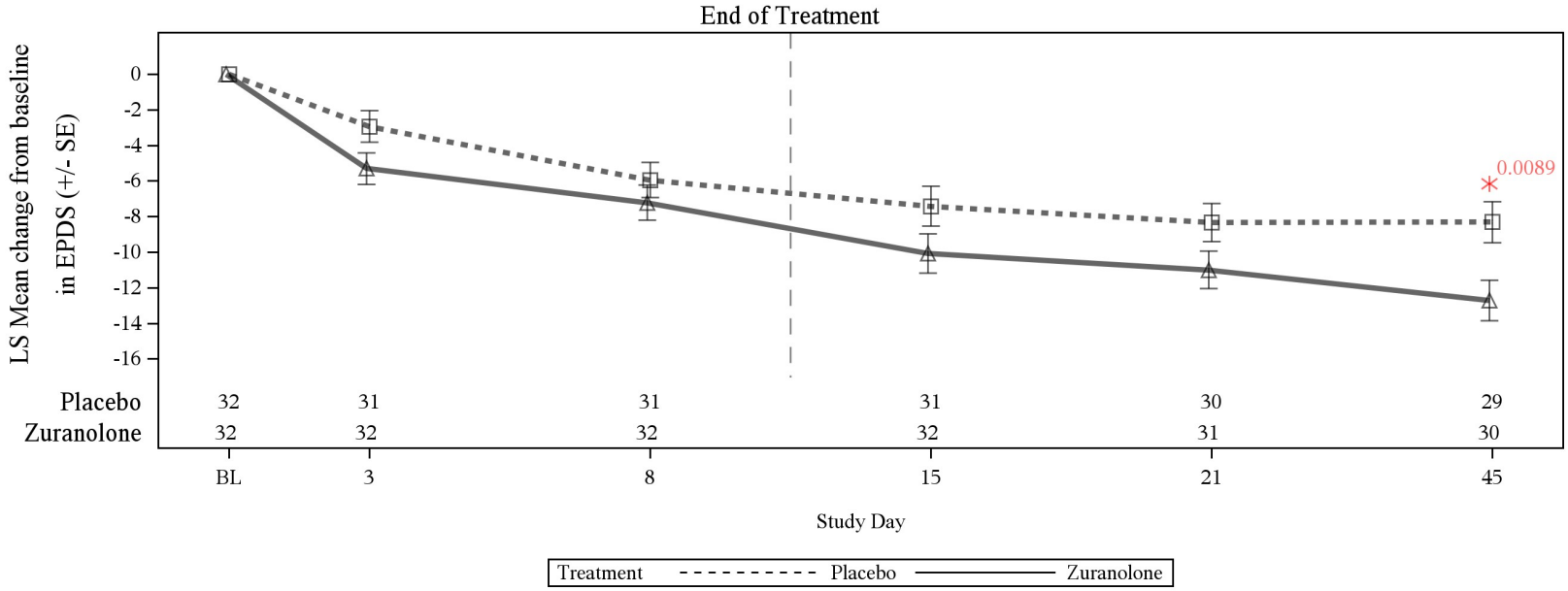
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

Page: 12 of 17

Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

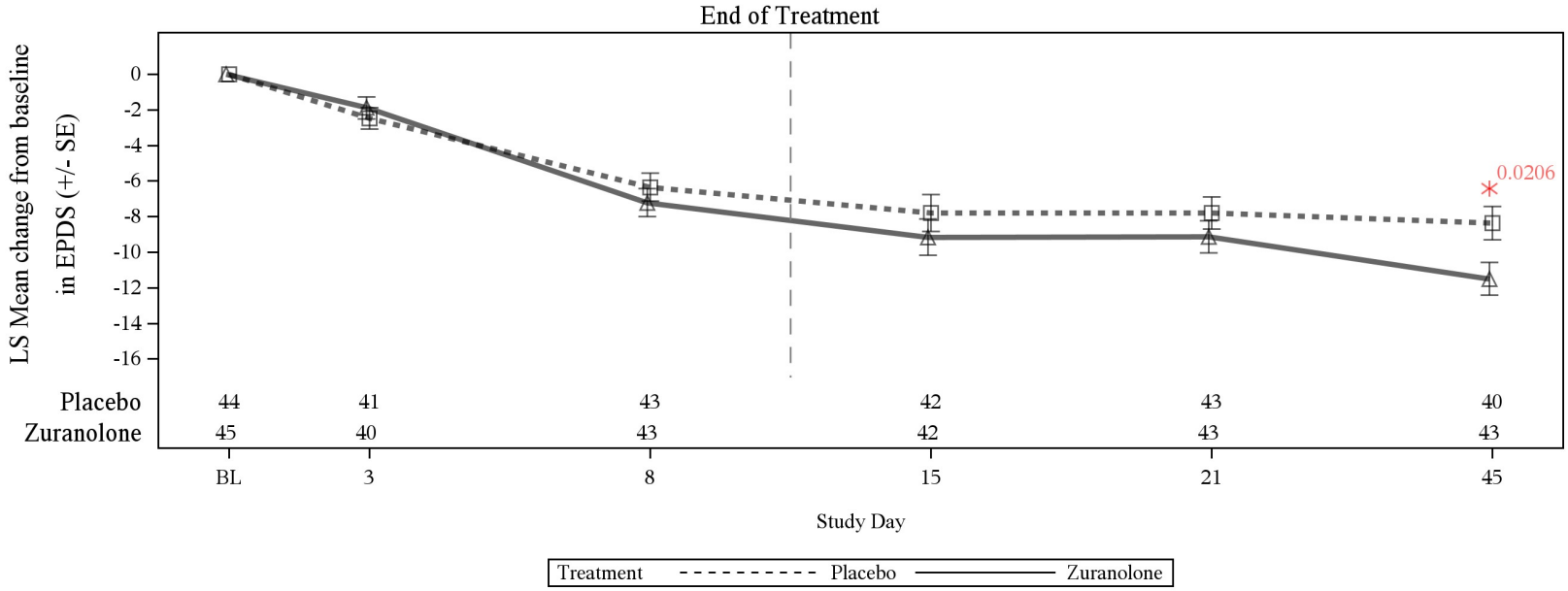
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

Page: 13 of 17

Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

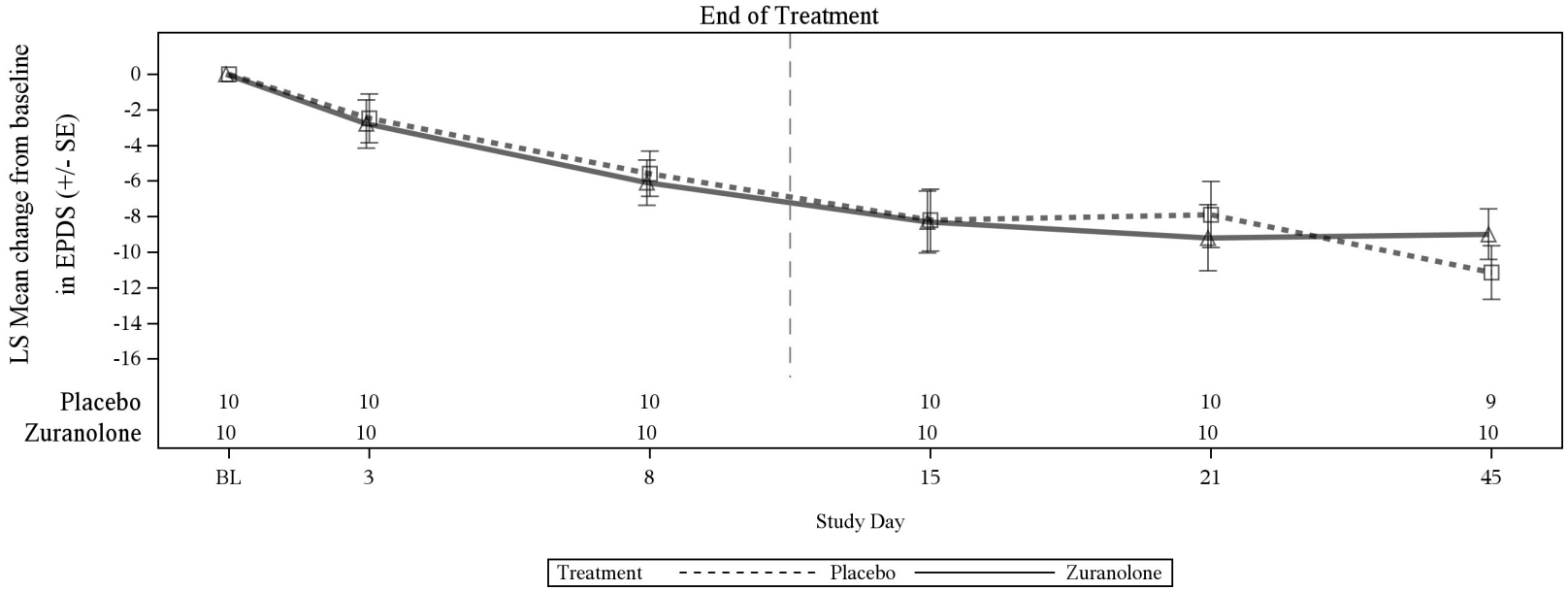
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

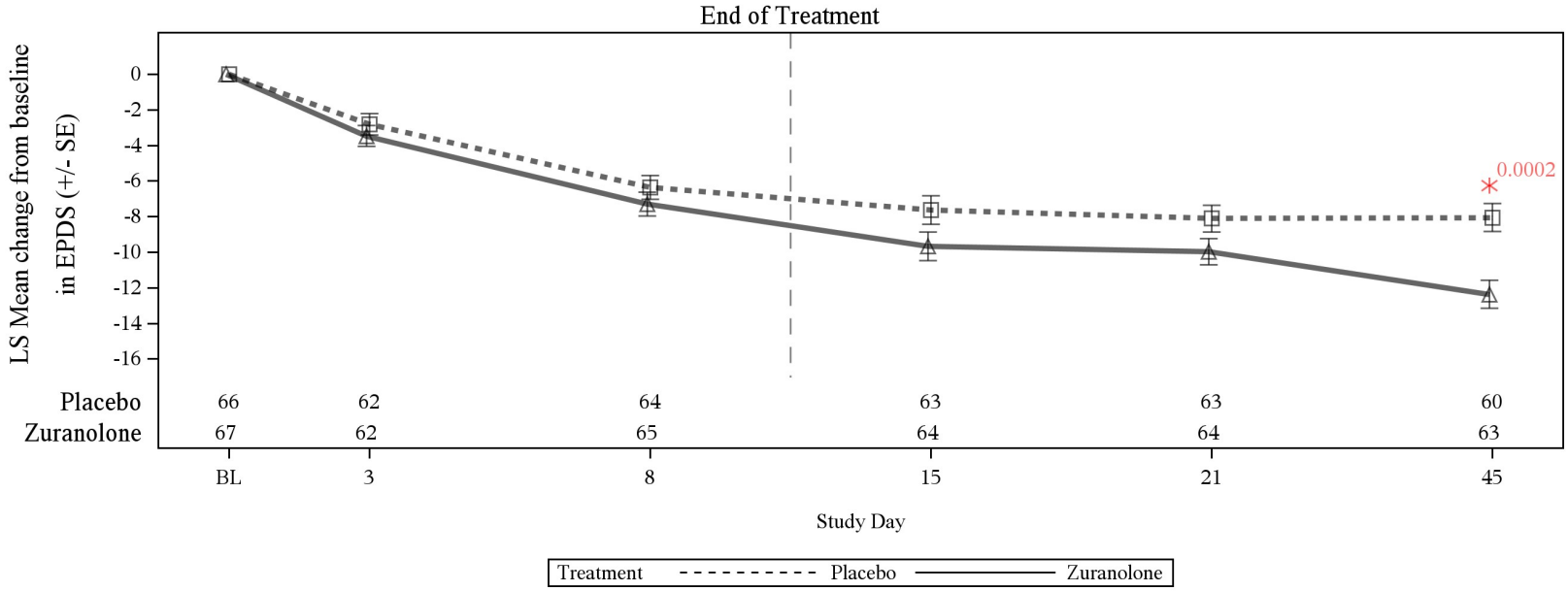
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

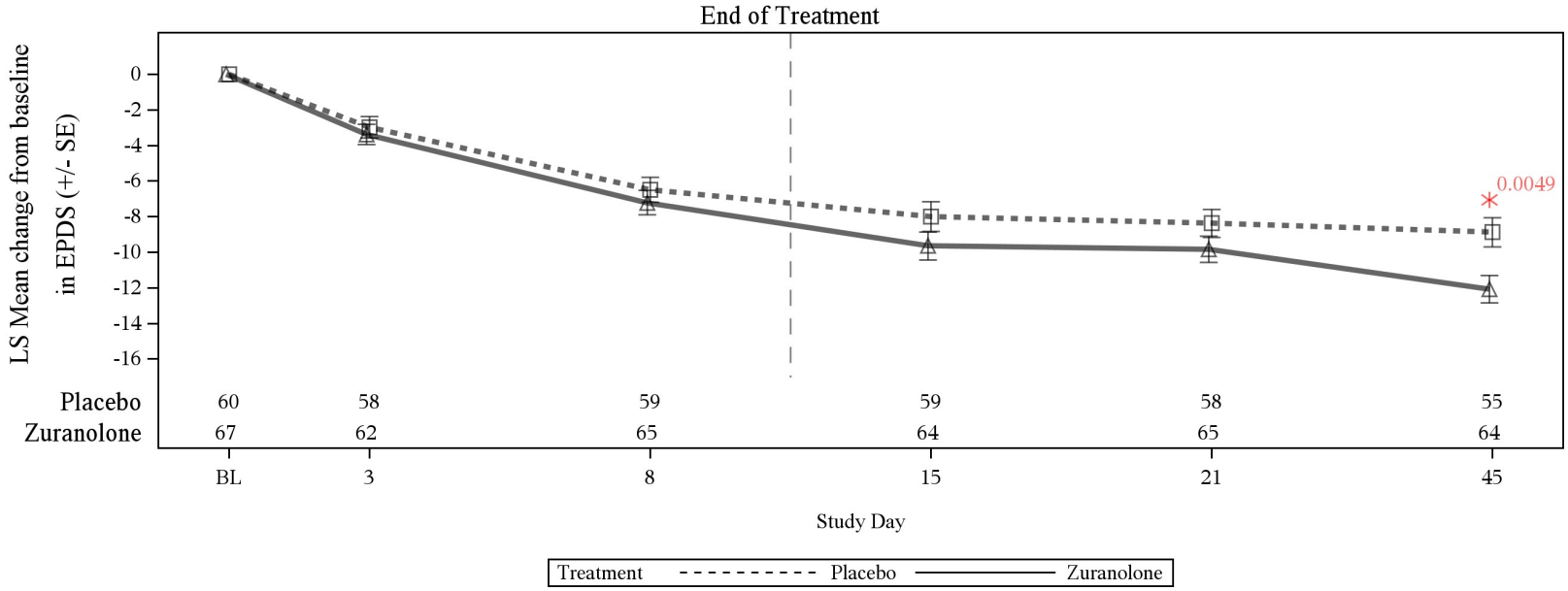
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

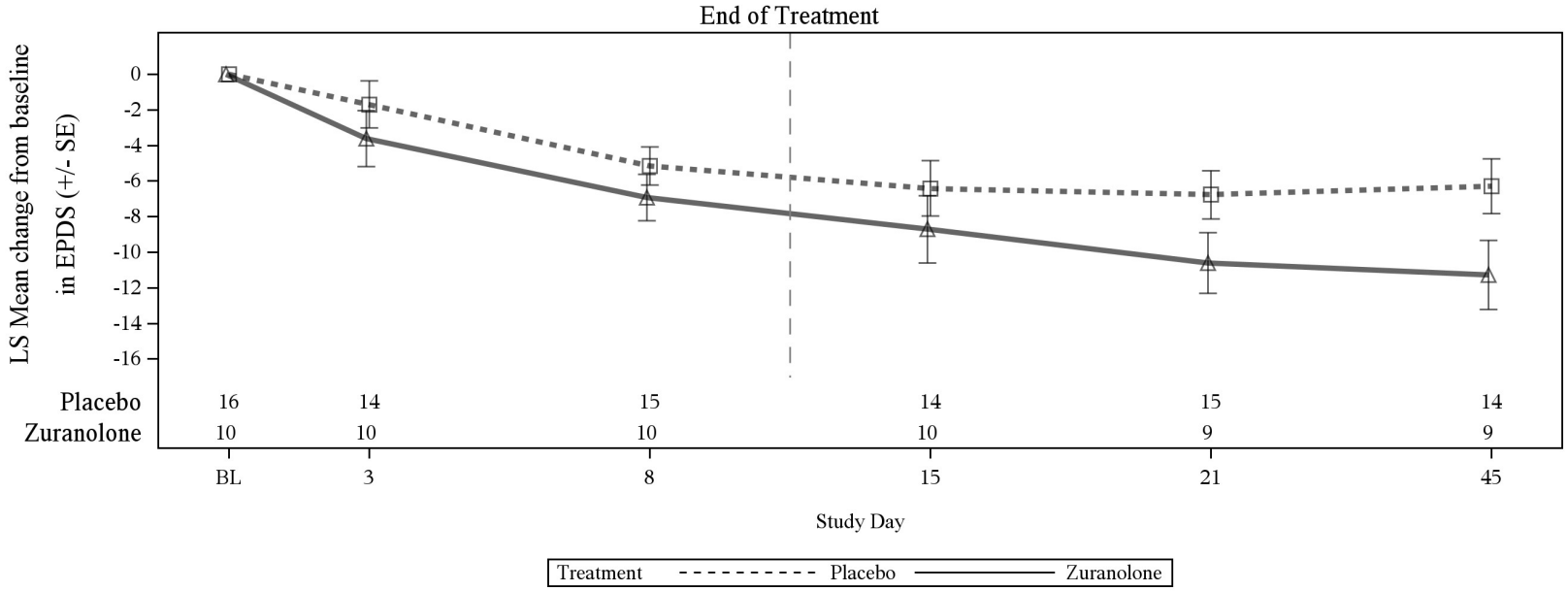
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-201-by.sas:f-epds-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

4.3.2 Ansprechen

4.3.2.1 Responder-Analysen

4.3.2.1 .1 ITT-Population

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with a response, n (%) [2]	19 (25.3)	18 (23.7)
Number of subjects with missing evaluation, n (%)	3 (4.0)	4 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.959
95% CI for the RR		(0.554, 1.660)
p-value for RR		0.8816
OR - Odds Ratio (Zuranolone vs. Placebo)		0.906
95% CI for the OR		(0.433, 1.896)
p-value for OR		0.7925
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-ovr.sas:t-epds-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with a response, n (%) [2]	45 (60.0)	45 (59.2)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.022
95% CI for the RR		(0.790, 1.322)
p-value for RR		0.8670
OR - Odds Ratio (Zuranolone vs. Placebo)		0.993
95% CI for the OR		(0.506, 1.950)
p-value for OR		0.9835
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

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Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with a response, n (%) [2]	47 (62.7)	56 (73.7)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.196
95% CI for the RR		(0.970, 1.473)
p-value for RR		0.0933
OR - Odds Ratio (Zuranolone vs. Placebo)		1.766
95% CI for the OR		(0.874, 3.569)
p-value for OR		0.1129
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-ovr.sas:t-epds-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with a response, n (%) [2]	53 (70.7)	57 (75.0)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.065
95% CI for the RR		(0.877, 1.292)
p-value for RR		0.5245
OR - Odds Ratio (Zuranolone vs. Placebo)		1.310
95% CI for the OR		(0.622, 2.755)
p-value for OR		0.4772
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-ovr.sas:t-epds-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	50 (66.7)	64 (84.2)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.219
95% CI for the RR		(1.018, 1.458)
p-value for RR		0.0309
OR - Odds Ratio (Zuranolone vs. Placebo)		2.861
95% CI for the OR		(1.287, 6.360)
p-value for OR		0.0099
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-ovr.sas:t-epds-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.3.2.1 .2 Subgruppen

4.3.2.1 .2 .1 Interaktionstest

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	47 (62.7)	56 (73.7)	
Number of subjects with response at Day 45, n (%)	50 (66.7)	64 (84.2)	
Age Group (years)			0.1598
Day 15			
18 - 24, n / N (%)	15/25 (60.0)	16/17 (94.1)	
25 - 45, n / N (%)	32/50 (64.0)	40/59 (67.8)	
Day 45			
18 - 24, n / N (%)	17/25 (68.0)	15/17 (88.2)	
25 - 45, n / N (%)	33/50 (66.0)	49/59 (83.1)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.3270
Day 15			
<28, n / N (%)	15/22 (68.2)	21/30 (70.0)	
>=28, n / N (%)	32/53 (60.4)	35/46 (76.1)	
Day 45			
<28, n / N (%)	17/22 (77.3)	25/30 (83.3)	
>=28, n / N (%)	33/53 (62.3)	39/46 (84.8)	
Race Group (Black or African American, White)			0.5050
Day 15			
Black or African American, n / N (%)	17/32 (53.1)	22/31 (71.0)	
White, n / N (%)	28/40 (70.0)	33/44 (75.0)	
Day 45			
Black or African American, n / N (%)	21/32 (65.6)	26/31 (83.9)	
White, n / N (%)	27/40 (67.5)	37/44 (84.1)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.1506
Day 15			
Yes, n / N (%)	6/13 (46.2)	12/16 (75.0)	
No, n / N (%)	41/62 (66.1)	44/60 (73.3)	
Day 45			
Yes, n / N (%)	8/13 (61.5)	14/16 (87.5)	
No, n / N (%)	42/62 (67.7)	50/60 (83.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-resp15-201-int.sas:t-epds-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.6674(a) 0.8184(b) 0.7800(c)
Day 15			
<=24.9, n / N (%)	13/21 (61.9)	10/13 (76.9)	
25-29.9, n / N (%)	14/20 (70.0)	15/21 (71.4)	
>=30, n / N (%)	20/34 (58.8)	31/42 (73.8)	
Day 45			
<=24.9, n / N (%)	12/21 (57.1)	12/13 (92.3)	
25-29.9, n / N (%)	15/20 (75.0)	17/21 (81.0)	
>=30, n / N (%)	23/34 (67.6)	35/42 (83.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.1025
Day 15			
3rd Trimester, n / N (%)	20/32 (62.5)	26/32 (81.3)	
Postpartum, n / N (%)	27/43 (62.8)	30/44 (68.2)	
Day 45			
3rd Trimester, n / N (%)	22/32 (68.8)	28/32 (87.5)	
Postpartum, n / N (%)	28/43 (65.1)	36/44 (81.8)	
Family History of PPD			0.6436
Day 15			
Yes, n / N (%)	8/10 (80.0)	7/10 (70.0)	
No/Unknown, n / N (%)	39/65 (60.0)	49/66 (74.2)	
Day 45			
Yes, n / N (%)	9/10 (90.0)	8/10 (80.0)	
No/Unknown, n / N (%)	41/65 (63.1)	56/66 (84.8)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.2679
Day 15			
1st Episode, n / N (%)	40/59 (67.8)	49/66 (74.2)	
Recurrent Episode, n / N (%)	7/16 (43.8)	7/10 (70.0)	
Day 45			
1st Episode, n / N (%)	42/59 (71.2)	55/66 (83.3)	
Recurrent Episode, n / N (%)	8/16 (50.0)	9/10 (90.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	5/8 (62.5)	8/10 (80.0)	
>=20, n / N (%)	42/67 (62.7)	48/66 (72.7)	
Day 45			
<20, n / N (%)	6/8 (75.0)	8/10 (80.0)	
>=20, n / N (%)	44/67 (65.7)	56/66 (84.8)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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4.3.2.1 .2 .2 Subgruppenanalysen

4.3.2.1 .2 .2 .1 Alter

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 3		
Number of subjects with a response, n (%) [2]	6 (24.0)	6 (35.3)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.457
95% CI for the RR		(0.560, 3.795)
p-value for RR		0.4406
Day 8		
Number of subjects with a response, n (%) [2]	15 (60.0)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.258
95% CI for the RR		(0.826, 1.916)
p-value for RR		0.2851

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 15		
Number of subjects with a response, n (%) [2]	15 (60.0)	16 (94.1)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.553
95% CI for the RR		(1.100, 2.191)
p-value for RR		0.0123
Day 21		
Number of subjects with a response, n (%) [2]	16 (64.0)	15 (88.2)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.390
95% CI for the RR		(1.007, 1.917)
p-value for RR		0.0451

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 45		
Number of subjects with a response, n (%) [2]	17 (68.0)	15 (88.2)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.285
95% CI for the RR		(0.934, 1.769)
p-value for RR		0.1231

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 4 of 6

Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 3		
Number of subjects with a response, n (%) [2]	13 (26.0)	12 (20.3)
Number of subjects with missing evaluation, n (%)	3 (6.0)	3 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.790
95% CI for the RR		(0.394, 1.585)
p-value for RR		0.5068
Day 8		
Number of subjects with a response, n (%) [2]	30 (60.0)	32 (54.2)
Number of subjects with missing evaluation, n (%)	1 (2.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.948
95% CI for the RR		(0.689, 1.304)
p-value for RR		0.7429

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 5 of 6

Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 15		
Number of subjects with a response, n (%) [2]	32 (64.0)	40 (67.8)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.096
95% CI for the RR		(0.847, 1.418)
p-value for RR		0.4851
Day 21		
Number of subjects with a response, n (%) [2]	37 (74.0)	42 (71.2)
Number of subjects with missing evaluation, n (%)	2 (4.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.987
95% CI for the RR		(0.794, 1.228)
p-value for RR		0.9065

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 45		
Number of subjects with a response, n (%) [2]	33 (66.0)	49 (83.1)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.244
95% CI for the RR		(1.003, 1.543)
p-value for RR		0.0470

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.3.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 3		
Number of subjects with a response, n (%) [2]	5 (22.7)	6 (20.0)
Number of subjects with missing evaluation, n (%)	2 (9.1)	4 (13.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.918
95% CI for the RR		(0.334, 2.520)
p-value for RR		0.8679
Day 8		
Number of subjects with a response, n (%) [2]	15 (68.2)	19 (63.3)
Number of subjects with missing evaluation, n (%)	0	1 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.907
95% CI for the RR		(0.632, 1.302)
p-value for RR		0.5962

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 2 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 15		
Number of subjects with a response, n (%) [2]	15 (68.2)	21 (70.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.043
95% CI for the RR		(0.754, 1.442)
p-value for RR		0.7995
Day 21		
Number of subjects with a response, n (%) [2]	17 (77.3)	18 (60.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.807
95% CI for the RR		(0.563, 1.157)
p-value for RR		0.2440

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 3 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 45		
Number of subjects with a response, n (%) [2]	17 (77.3)	25 (83.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.050
95% CI for the RR		(0.806, 1.367)
p-value for RR		0.7184

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 3		
Number of subjects with a response, n (%) [2]	14 (26.4)	12 (26.1)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.999
95% CI for the RR		(0.521, 1.915)
p-value for RR		0.9980
Day 8		
Number of subjects with a response, n (%) [2]	30 (56.6)	26 (56.5)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.026
95% CI for the RR		(0.732, 1.438)
p-value for RR		0.8826

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 15		
Number of subjects with a response, n (%) [2]	32 (60.4)	35 (76.1)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.261
95% CI for the RR		(0.974, 1.632)
p-value for RR		0.0784
Day 21		
Number of subjects with a response, n (%) [2]	36 (67.9)	39 (84.8)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.199
95% CI for the RR		(0.968, 1.484)
p-value for RR		0.0965

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.
[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 6 of 6

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 45		
Number of subjects with a response, n (%) [2]	33 (62.3)	39 (84.8)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.334
95% CI for the RR		(1.060, 1.679)
p-value for RR		0.0142

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure and "Log" link function.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.3.2.1 .2 .2 .3 Abstammung

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 3		
Number of subjects with a response, n (%) [2]	8 (25.0)	7 (22.6)
Number of subjects with missing evaluation, n (%)	1 (3.1)	2 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.911
95% CI for the RR		(0.380, 2.184)
p-value for RR		0.8349
Day 8		
Number of subjects with a response, n (%) [2]	17 (53.1)	19 (61.3)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.164
95% CI for the RR		(0.769, 1.761)
p-value for RR		0.4723

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 2 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 15		
Number of subjects with a response, n (%) [2]	17 (53.1)	22 (71.0)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.348
95% CI for the RR		(0.919, 1.977)
p-value for RR		0.1268
Day 21		
Number of subjects with a response, n (%) [2]	21 (65.6)	23 (74.2)
Number of subjects with missing evaluation, n (%)	1 (3.1)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.141
95% CI for the RR		(0.826, 1.575)
p-value for RR		0.4245

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 45		
Number of subjects with a response, n (%) [2]	21 (65.6)	26 (83.9)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.289
95% CI for the RR		(0.960, 1.731)
p-value for RR		0.0911

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 4 of 6

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 3		
Number of subjects with a response, n (%) [2]	11 (27.5)	10 (22.7)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.842
95% CI for the RR		(0.410, 1.727)
p-value for RR		0.6385
Day 8		
Number of subjects with a response, n (%) [2]	26 (65.0)	25 (56.8)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.890
95% CI for the RR		(0.631, 1.256)
p-value for RR		0.5075

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 5 of 6

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	28 (70.0)	33 (75.0)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.091
95% CI for the RR		(0.853, 1.397)
p-value for RR		0.4883
Day 21		
Number of subjects with a response, n (%) [2]	30 (75.0)	34 (77.3)
Number of subjects with missing evaluation, n (%)	1 (2.5)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.049
95% CI for the RR		(0.832, 1.323)
p-value for RR		0.6837

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 6 of 6

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	27 (67.5)	37 (84.1)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.269
95% CI for the RR		(0.991, 1.624)
p-value for RR		0.0591

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.3.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 6

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 3		
Number of subjects with a response, n (%) [2]	1 (7.7)	3 (18.8)
Number of subjects with missing evaluation, n (%)	0	2 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		2.605
95% CI for the RR		(0.306, 22.137)
p-value for RR		0.3806
Day 8		
Number of subjects with a response, n (%) [2]	7 (53.8)	9 (56.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.116
95% CI for the RR		(0.596, 2.090)
p-value for RR		0.7311

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 15		
Number of subjects with a response, n (%) [2]	6 (46.2)	12 (75.0)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.736
95% CI for the RR		(0.924, 3.262)
p-value for RR		0.0863
Day 21		
Number of subjects with a response, n (%) [2]	8 (61.5)	12 (75.0)
Number of subjects with missing evaluation, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.302
95% CI for the RR		(0.778, 2.180)
p-value for RR		0.3148

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 45		
Number of subjects with a response, n (%) [2]	8 (61.5)	14 (87.5)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.519
95% CI for the RR		(0.946, 2.441)
p-value for RR		0.0838

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 3		
Number of subjects with a response, n (%) [2]	18 (29.0)	15 (25.0)
Number of subjects with missing evaluation, n (%)	3 (4.8)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.858
95% CI for the RR		(0.482, 1.528)
p-value for RR		0.6039
Day 8		
Number of subjects with a response, n (%) [2]	38 (61.3)	36 (60.0)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.976
95% CI for the RR		(0.733, 1.299)
p-value for RR		0.8671

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 15		
Number of subjects with a response, n (%) [2]	41 (66.1)	44 (73.3)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.105
95% CI for the RR		(0.878, 1.391)
p-value for RR		0.3929
Day 21		
Number of subjects with a response, n (%) [2]	45 (72.6)	45 (75.0)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.030
95% CI for the RR		(0.833, 1.274)
p-value for RR		0.7845

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 45		
Number of subjects with a response, n (%) [2]	42 (67.7)	50 (83.3)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.226
95% CI for the RR		(1.000, 1.503)
p-value for RR		0.0495

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.3.2.1 .2 .2 .5 BMI

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 3		
Number of subjects with a response, n (%) [2]	7 (33.3)	3 (23.1)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.612
95% CI for the RR		(0.204, 1.839)
p-value for RR		0.3818
Day 8		
Number of subjects with a response, n (%) [2]	14 (66.7)	9 (69.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.918
95% CI for the RR		(0.581, 1.451)
p-value for RR		0.7147

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 15		
Number of subjects with a response, n (%) [2]	13 (61.9)	10 (76.9)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.099
95% CI for the RR		(0.722, 1.673)
p-value for RR		0.6607
Day 21		
Number of subjects with a response, n (%) [2]	13 (61.9)	9 (69.2)
Number of subjects with missing evaluation, n (%)	2 (9.5)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.989
95% CI for the RR		(0.607, 1.612)
p-value for RR		0.9642

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 45		
Number of subjects with a response, n (%) [2]	12 (57.1)	12 (92.3)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.428
95% CI for the RR		(0.928, 2.198)
p-value for RR		0.1048

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 3		
Number of subjects with a response, n (%) [2]	3 (15.0)	5 (23.8)
Number of subjects with missing evaluation, n (%)	1 (5.0)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.040
95% CI for the RR		(0.200, 5.414)
p-value for RR		0.9624
Day 8		
Number of subjects with a response, n (%) [2]	13 (65.0)	11 (52.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.528
95% CI for the RR		(0.228, 1.222)
p-value for RR		0.1359

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	14 (70.0)	15 (71.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.669
95% CI for the RR		(0.307, 1.458)
p-value for RR		0.3116
Day 21		
Number of subjects with a response, n (%) [2]	14 (70.0)	17 (81.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.758
95% CI for the RR		(0.365, 1.574)
p-value for RR		0.4574

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 45		
Number of subjects with a response, n (%) [2]	15 (75.0)	17 (81.0)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.708
95% CI for the RR		(0.331, 1.515)
p-value for RR		0.3730

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 3		
Number of subjects with a response, n (%) [2]	9 (26.5)	10 (23.8)
Number of subjects with missing evaluation, n (%)	1 (2.9)	3 (7.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.907
95% CI for the RR		(0.421, 1.953)
p-value for RR		0.8034
Day 8		
Number of subjects with a response, n (%) [2]	18 (52.9)	25 (59.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.134
95% CI for the RR		(0.757, 1.698)
p-value for RR		0.5416

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 15		
Number of subjects with a response, n (%) [2]	20 (58.8)	31 (73.8)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.266
95% CI for the RR		(0.908, 1.763)
p-value for RR		0.1642
Day 21		
Number of subjects with a response, n (%) [2]	26 (76.5)	31 (73.8)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.973
95% CI for the RR		(0.750, 1.264)
p-value for RR		0.8402

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 45		
Number of subjects with a response, n (%) [2]	23 (67.6)	35 (83.3)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.242
95% CI for the RR		(0.955, 1.617)
p-value for RR		0.1063

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.3.2.1 .2 .2 .6 Beginn der PPD

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 3		
Number of subjects with a response, n (%) [2]	10 (31.3)	13 (40.6)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.328
95% CI for the RR		(0.700, 2.518)
p-value for RR		0.3853
Day 8		
Number of subjects with a response, n (%) [2]	17 (53.1)	19 (59.4)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.141
95% CI for the RR		(0.743, 1.753)
p-value for RR		0.5456

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 15		
Number of subjects with a response, n (%) [2]	20 (62.5)	26 (81.3)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.328
95% CI for the RR		(0.967, 1.824)
p-value for RR		0.0802
Day 21		
Number of subjects with a response, n (%) [2]	23 (71.9)	27 (84.4)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.199
95% CI for the RR		(0.911, 1.577)
p-value for RR		0.1947

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 45		
Number of subjects with a response, n (%) [2]	22 (68.8)	28 (87.5)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.300
95% CI for the RR		(0.994, 1.701)
p-value for RR		0.0558

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 3		
Number of subjects with a response, n (%) [2]	9 (20.9)	5 (11.4)
Number of subjects with missing evaluation, n (%)	2 (4.7)	4 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.548
95% CI for the RR		(0.201, 1.494)
p-value for RR		0.2399
Day 8		
Number of subjects with a response, n (%) [2]	28 (65.1)	26 (59.1)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.917
95% CI for the RR		(0.660, 1.274)
p-value for RR		0.6040

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	27 (62.8)	30 (68.2)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.097
95% CI for the RR		(0.812, 1.482)
p-value for RR		0.5468
Day 21		
Number of subjects with a response, n (%) [2]	30 (69.8)	30 (68.2)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.987
95% CI for the RR		(0.745, 1.308)
p-value for RR		0.9282

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	28 (65.1)	36 (81.8)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.269
95% CI for the RR		(0.978, 1.646)
p-value for RR		0.0725

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.3.2.1 .2 .2 .7 PPD in der Familie

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 3		
Number of subjects with a response, n (%) [2]	2 (20.0)	2 (20.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.198
95% CI for the RR		(0.092, 15.583)
p-value for RR		0.8900
Day 8		
Number of subjects with a response, n (%) [2]	7 (70.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.027
95% CI for the RR		(0.200, 5.282)
p-value for RR		0.9743

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	8 (80.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.049
95% CI for the RR		(0.232, 4.732)
p-value for RR		0.9507
Day 21		
Number of subjects with a response, n (%) [2]	8 (80.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.049
95% CI for the RR		(0.245, 4.480)
p-value for RR		0.9489

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	9 (90.0)	8 (80.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.065
95% CI for the RR		(0.264, 4.300)
p-value for RR		0.9292

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 3		
Number of subjects with a response, n (%) [2]	17 (26.2)	16 (24.2)
Number of subjects with missing evaluation, n (%)	3 (4.6)	4 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.923
95% CI for the RR		(0.515, 1.654)
p-value for RR		0.7868
Day 8		
Number of subjects with a response, n (%) [2]	38 (58.5)	39 (59.1)
Number of subjects with missing evaluation, n (%)	1 (1.5)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.006
95% CI for the RR		(0.757, 1.336)
p-value for RR		0.9667

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	39 (60.0)	49 (74.2)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.232
95% CI for the RR		(0.970, 1.564)
p-value for RR		0.0877
Day 21		
Number of subjects with a response, n (%) [2]	45 (69.2)	50 (75.8)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.089
95% CI for the RR		(0.881, 1.346)
p-value for RR		0.4295

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	41 (63.1)	56 (84.8)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.339
95% CI for the RR		(1.085, 1.653)
p-value for RR		0.0066

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.3.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 3		
Number of subjects with a response, n (%) [2]	15 (25.4)	16 (24.2)
Number of subjects with missing evaluation, n (%)	1 (1.7)	4 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.955
95% CI for the RR		(0.522, 1.747)
p-value for RR		0.8810
Day 8		
Number of subjects with a response, n (%) [2]	39 (66.1)	40 (60.6)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.918
95% CI for the RR		(0.704, 1.197)
p-value for RR		0.5281

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	40 (67.8)	49 (74.2)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.097
95% CI for the RR		(0.879, 1.369)
p-value for RR		0.4145
Day 21		
Number of subjects with a response, n (%) [2]	43 (72.9)	50 (75.8)
Number of subjects with missing evaluation, n (%)	1 (1.7)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.041
95% CI for the RR		(0.846, 1.280)
p-value for RR		0.7036

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	42 (71.2)	55 (83.3)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.172
95% CI for the RR		(0.967, 1.422)
p-value for RR		0.1064

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 3		
Number of subjects with a response, n (%) [2]	4 (25.0)	2 (20.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.795
95% CI for the RR		(0.197, 3.199)
p-value for RR		0.7463
Day 8		
Number of subjects with a response, n (%) [2]	6 (37.5)	5 (50.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.324
95% CI for the RR		(0.610, 2.877)
p-value for RR		0.4778

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	7 (43.8)	7 (70.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.589
95% CI for the RR		(0.847, 2.982)
p-value for RR		0.1491
Day 21		
Number of subjects with a response, n (%) [2]	10 (62.5)	7 (70.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.112
95% CI for the RR		(0.597, 2.073)
p-value for RR		0.7371

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	8 (50.0)	9 (90.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.788
95% CI for the RR		(1.003, 3.186)
p-value for RR		0.0487

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response (4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

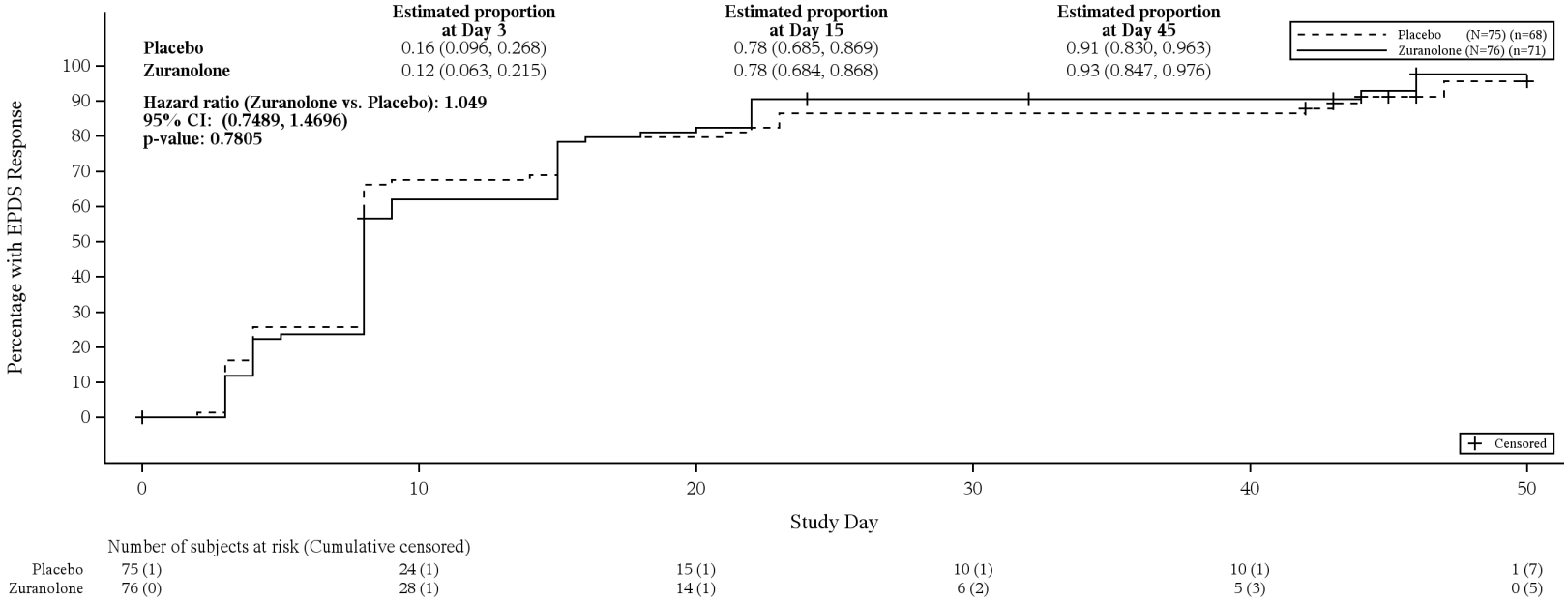
Source: biib125/v_a/germany_amnog/t-epds-resp15-201-by.sas:t-epds-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.3.2.2 TTE-Analysen

4.3.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-ovr.sas:f-epds-resp15-tte-201-ovr-itta.rtf **Run Date:** 16DEC2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	68 (90.7)	71 (93.4)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	8.0 (NE, NE)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 23.0)	15.0 (15.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.049
95% CI for the HR		(0.7489 , 1.4696)
p-value for the HR		0.7805

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-ovr.sas:t-epds-resp15-tte-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.3.2.2 .2 Subgruppen

4.3.2.2 .2 .1 Interaktionstest

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	68 (90.7)	71 (93.4)	
Age Group (years)			
18 - 24, n / N (%)	24/25 (96.0)	17/17 (100.0)	0.3013
25 - 45, n / N (%)	44/50 (88.0)	54/59 (91.5)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	21/22 (95.5)	27/30 (90.0)	0.4104
>=28, n / N (%)	47/53 (88.7)	44/46 (95.7)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	28/32 (87.5)	30/31 (96.8)	0.2713
White, n / N (%)	38/40 (95.0)	40/44 (90.9)	
Antidepressant Use at Baseline			
Yes, n / N (%)	11/13 (84.6)	15/16 (93.8)	0.1604
No, n / N (%)	57/62 (91.9)	56/60 (93.3)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-int.sas:t-epds-resp15-tte-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	18/21 (85.7)	13/13 (100.0)	0.6297(a)
25-29.9, n / N (%)	18/20 (90.0)	19/21 (90.5)	0.9508(b)
>=30, n / N (%)	32/34 (94.1)	39/42 (92.9)	0.5142(c)
Onset of PPD			
3rd Trimester, n / N (%)	30/32 (93.8)	31/32 (96.9)	0.6088
Postpartum, n / N (%)	38/43 (88.4)	40/44 (90.9)	
Family History of PPD			
Yes, n / N (%)	10/10 (100.0)	9/10 (90.0)	0.3747
No/Unknown, n / N (%)	58/65 (89.2)	62/66 (93.9)	
History of PPD			
1st Episode, n / N (%)	55/59 (93.2)	61/66 (92.4)	0.2520
Recurrent Episode, n / N (%)	13/16 (81.3)	10/10 (100.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	7/8 (87.5)	9/10 (90.0)	NA
>=20, n / N (%)	61/67 (91.0)	62/66 (93.9)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-int.sas:t-epds-resp15-tte-201-int-itta.rtf **Run Date:** 29JUL2025

4.3.2.2 .2 .2 Subgruppenanalysen

4.3.2.2 .2 .2 .1 Alter

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	24 (96.0)	17 (100.0)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 43.0)	8.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.546
95% CI for the HR		(0.7883 , 3.0306)
p-value for the HR		0.2049

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	44 (88.0)	54 (91.5)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	8.0 (NE, NE)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 23.0)	18.0 (15.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.980
95% CI for the HR		(0.6505 , 1.4755)
p-value for the HR		0.9220

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.3.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	21 (95.5)	27 (90.0)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (2.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 42.0)	22.0 (8.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.850
95% CI for the HR		(0.4730 , 1.5289)
p-value for the HR		0.5882

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	47 (88.7)	44 (95.7)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (NE, NE)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 43.0)	15.0 (15.0 , 20.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.122
95% CI for the HR		(0.7368 , 1.7086)
p-value for the HR		0.5916

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.3.2.2 .2 .2 .3 Abstammung

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	28 (87.5)	30 (96.8)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	21.0 (8.0 , 47.0)	15.0 (9.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.197
95% CI for the HR		(0.7067 , 2.0261)
p-value for the HR		0.5042

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	38 (95.0)	40 (90.9)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (NE, NE)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 23.0)	15.0 (15.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.868
95% CI for the HR		(0.5514 , 1.3678)
p-value for the HR		0.5428

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.3.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	11 (84.6)	15 (93.8)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 9.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	9.0 (8.0 , 23.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	23.0 (8.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.774
95% CI for the HR		(0.7647 , 4.1146)
p-value for the HR		0.1819

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	57 (91.9)	56 (93.3)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	6.5 (4.0 , 8.0)
50th percentile - median (95% CI)	8.0 (NE, NE)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 21.0)	15.0 (9.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.939
95% CI for the HR		(0.6478 , 1.3621)
p-value for the HR		0.7413

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.3.2.2 .2 .2 .5 BMI

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	18 (85.7)	13 (100.0)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (4.0 , 8.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	11.5 (8.0, NE)	8.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.791
95% CI for the HR		(0.3664 , 1.7077)
p-value for the HR		0.5504

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	18 (90.0)	19 (90.5)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (2.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	15.0 (8.0, NE)	15.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.139
95% CI for the HR		(0.5466 , 2.3750)
p-value for the HR		0.7278

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

Page: 3 of 3

BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	32 (94.1)	39 (92.9)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 23.0)	15.0 (9.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.947
95% CI for the HR		(0.5888 , 1.5231)
p-value for the HR		0.8223

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.3.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	30 (93.8)	31 (96.9)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 5.0)
50th percentile - median (95% CI)	8.0 (4.0 , 8.0)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 23.0)	15.0 (9.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.269
95% CI for the HR		(0.7421 , 2.1706)
p-value for the HR		0.3841

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	38 (88.4)	40 (90.9)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	8.0 (NE, NE)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 43.0)	15.0 (9.0 , 44.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.958
95% CI for the HR		(0.6134 , 1.4950)
p-value for the HR		0.8489

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.3.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	10 (100.0)	9 (90.0)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (3.0 , 8.0)	8.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	8.0 (8.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.771
95% CI for the HR		(0.2732 , 2.1735)
p-value for the HR		0.6224

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	58 (89.2)	62 (93.9)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	8.0 (NE, NE)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	15.5 (9.0 , 42.0)	15.0 (15.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.103
95% CI for the HR		(0.7668 , 1.5877)
p-value for the HR		0.5960

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.3.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	55 (93.2)	61 (92.4)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	8.0 (NE, NE)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 23.0)	15.0 (9.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.928
95% CI for the HR		(0.6423 , 1.3421)
p-value for the HR		0.6929

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-201-by.sas:t-epds-resp15-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	13 (81.3)	10 (100.0)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	8.0 (3.0 , 15.0)
50th percentile - median (95% CI)	8.0 (3.0 , 21.0)	11.5 (3.0 , 18.0)
75th percentile - Q3 (95% CI)	23.0 (8.0, NE)	18.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.966
95% CI for the HR		(0.7534 , 5.1313)
p-value for the HR		0.1671

NOTE 1: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

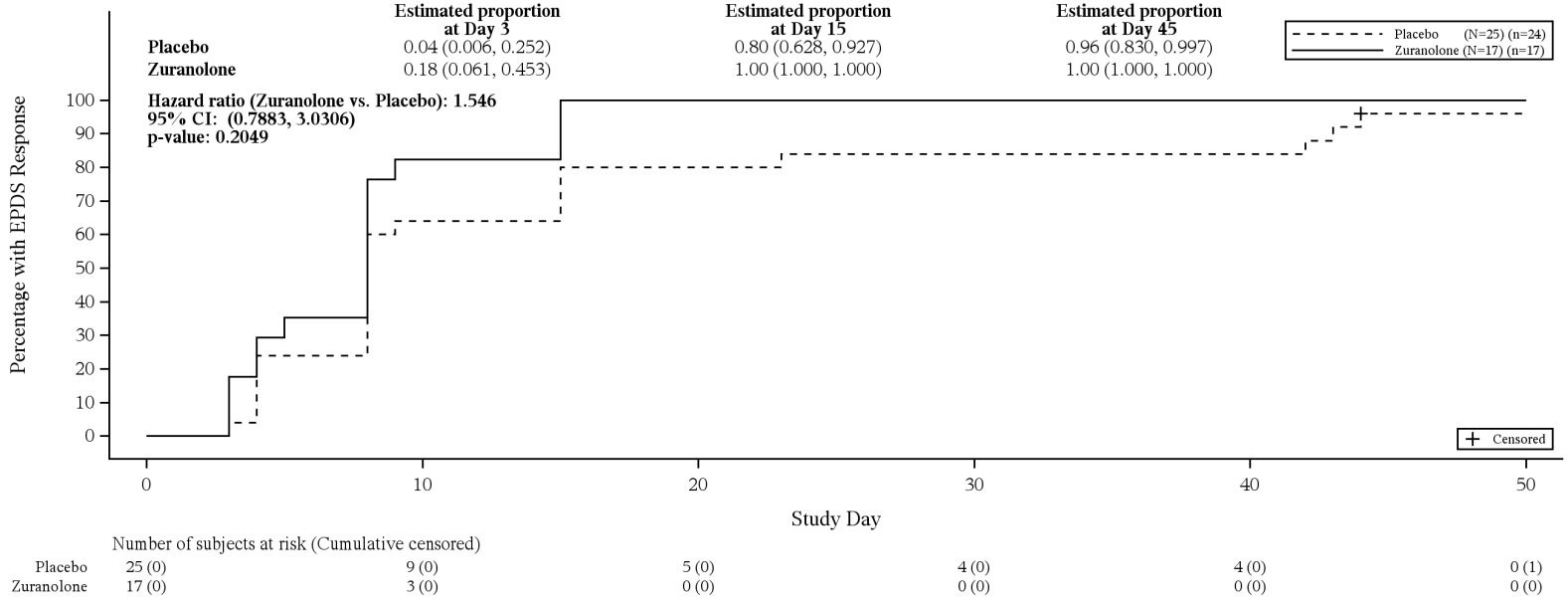
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4.3.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 19

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

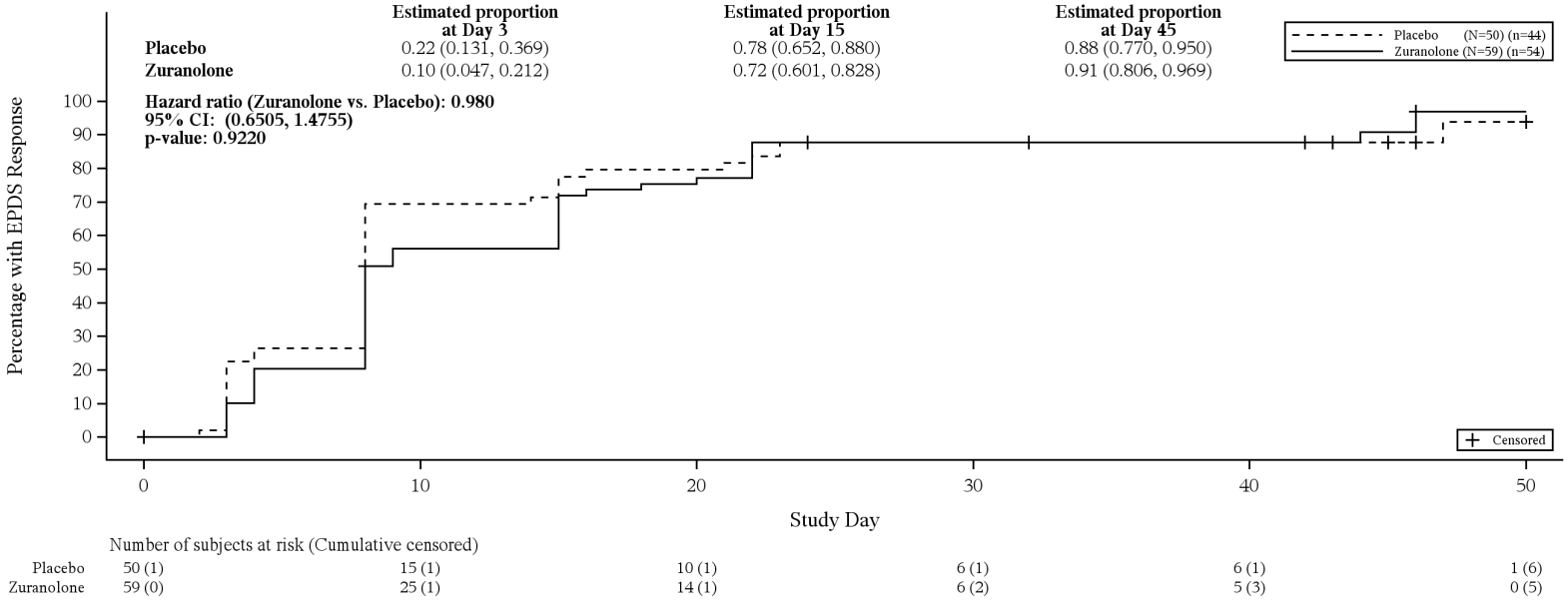
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 25-45



Number of subjects at risk (Cumulative censored)

Placebo	50 (1)	15 (1)	10 (1)	6 (1)	6 (1)	1 (6)
Zuranolone	59 (0)	25 (1)	14 (1)	6 (2)	5 (3)	0 (5)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

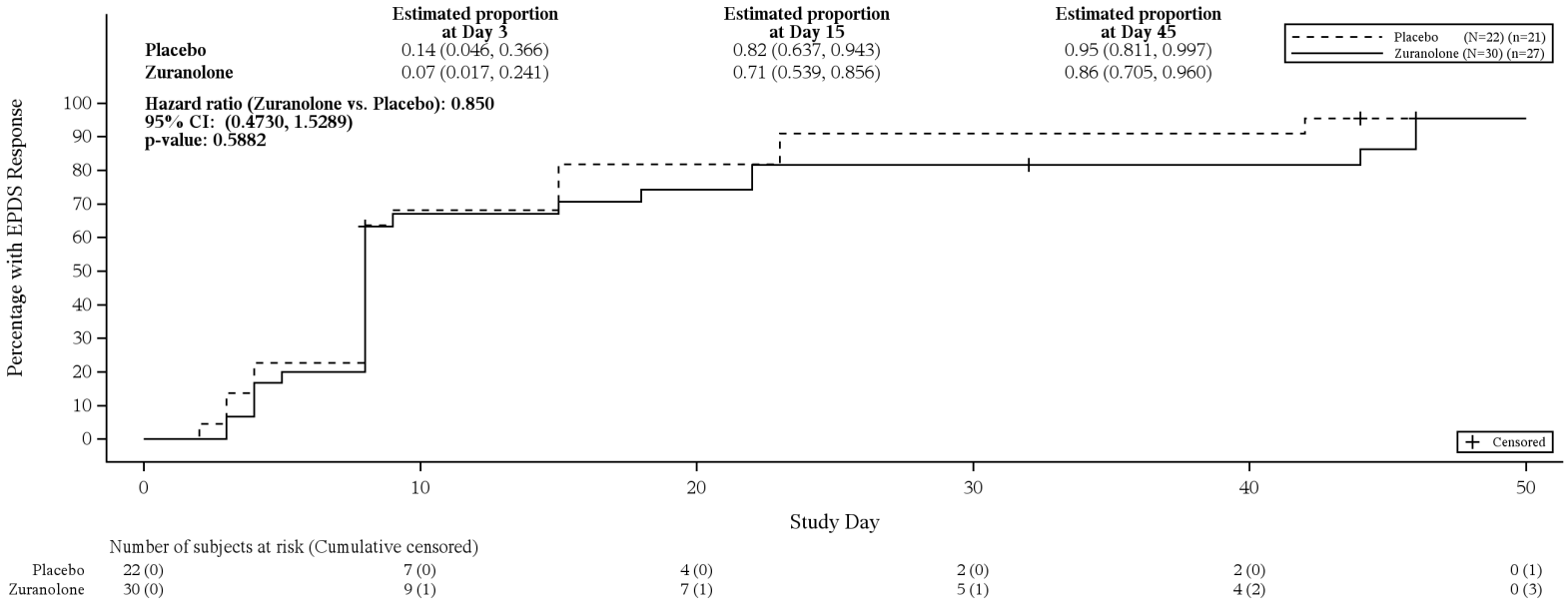
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	7 (0)	4 (0)	2 (0)	2 (0)	0 (1)
Zuranolone	30 (0)	9 (1)	7 (1)	5 (1)	4 (2)	0 (3)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

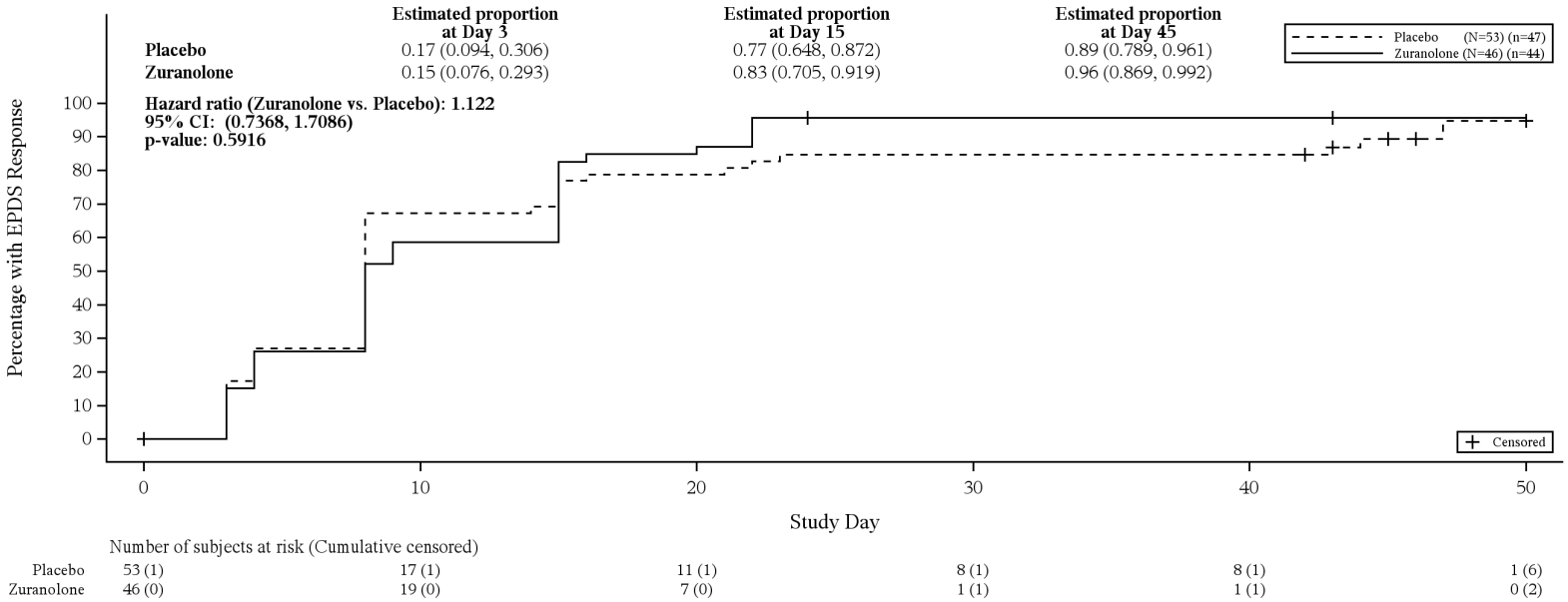
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	53 (1)	17 (1)	11 (1)	8 (1)	8 (1)	1 (6)
Zuranolone	46 (0)	19 (0)	7 (0)	1 (1)	1 (1)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

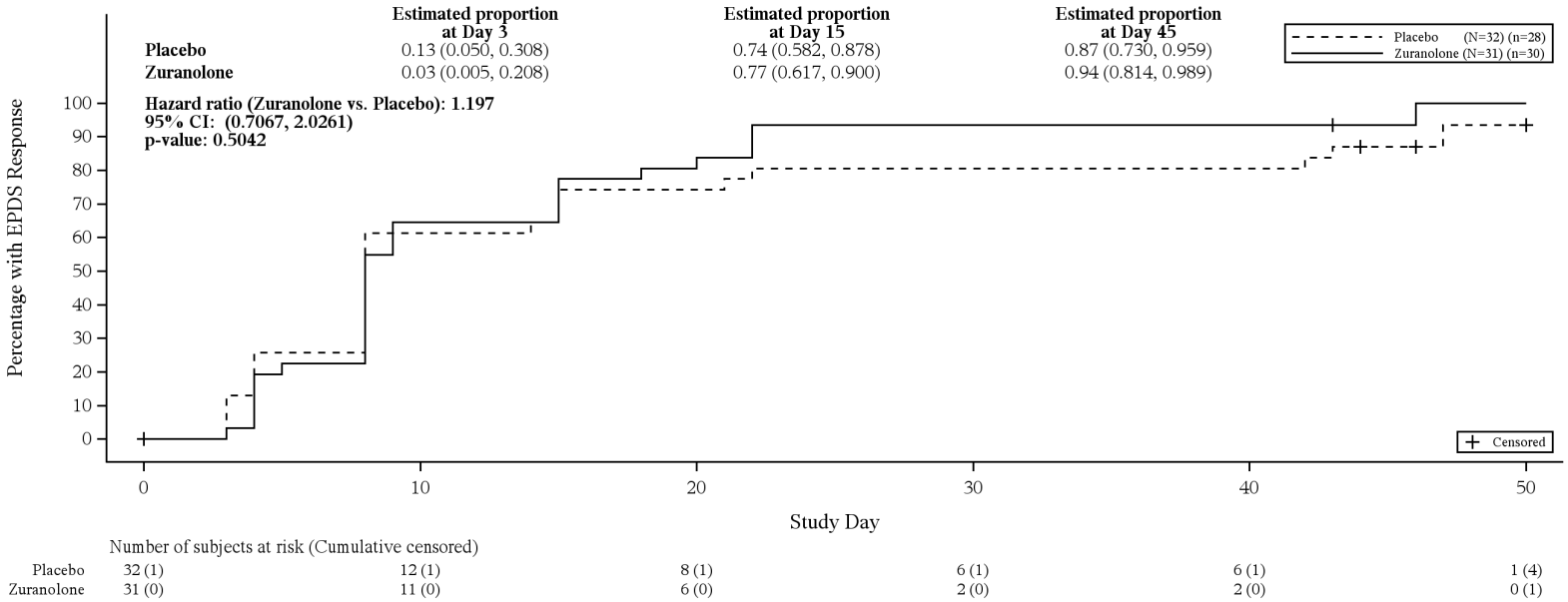
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Number of subjects at risk (Cumulative censored)

Placebo	32 (1)	12 (1)	8 (1)	6 (1)	6 (1)	1 (4)
Zuranolone	31 (0)	11 (0)	6 (0)	2 (0)	2 (0)	0 (1)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

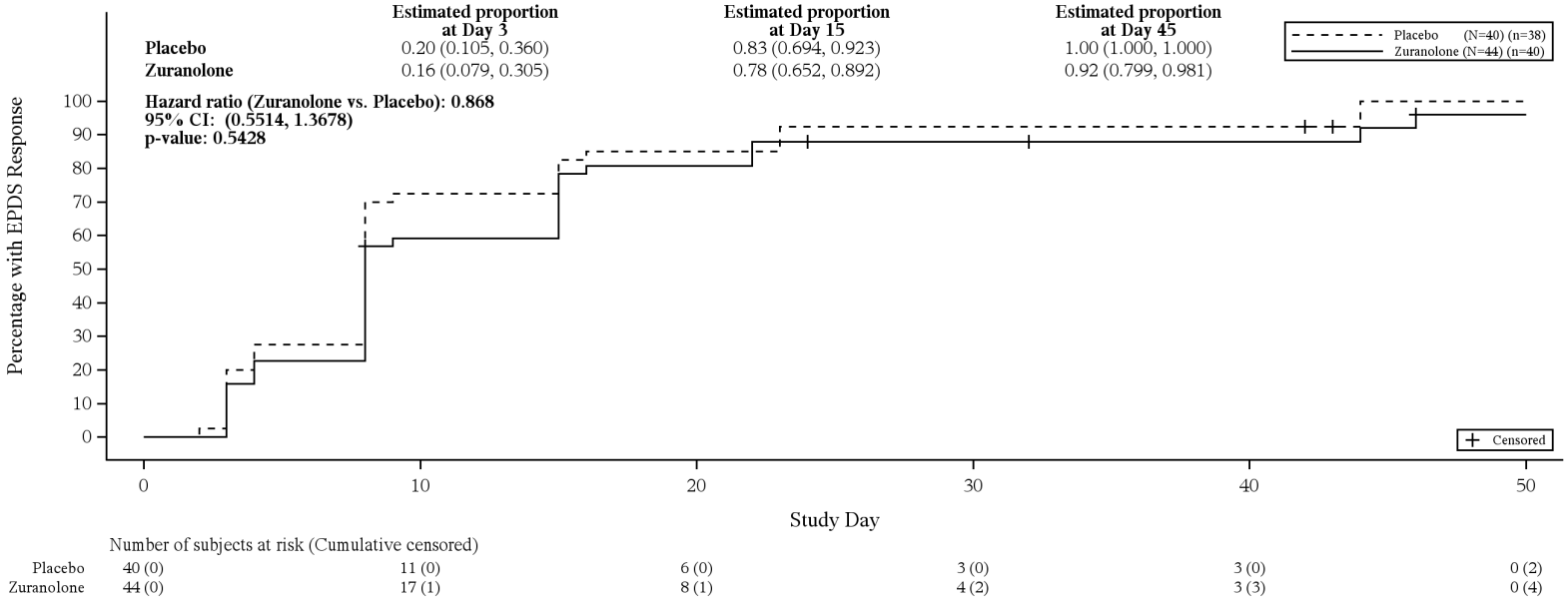
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

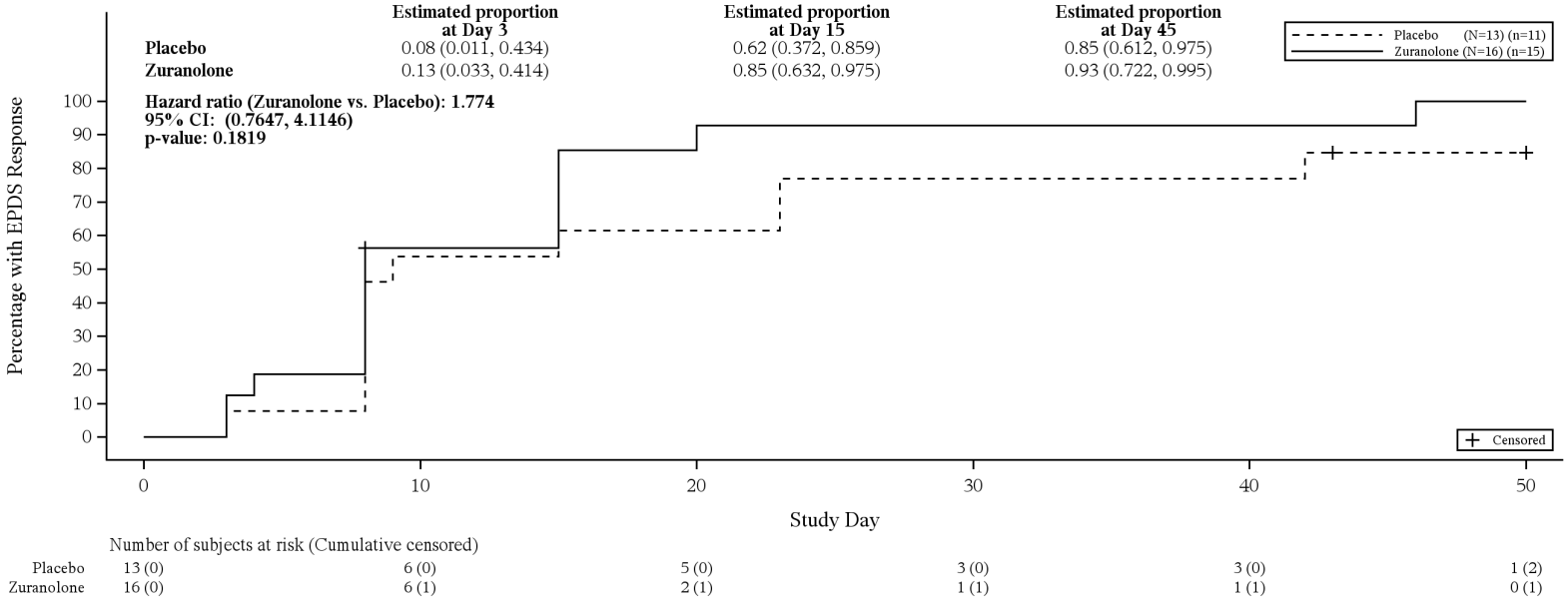
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	13 (0)	6 (0)	5 (0)	3 (0)	3 (0)	1 (2)
Zuranolone	16 (0)	6 (1)	2 (1)	1 (1)	1 (1)	0 (1)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

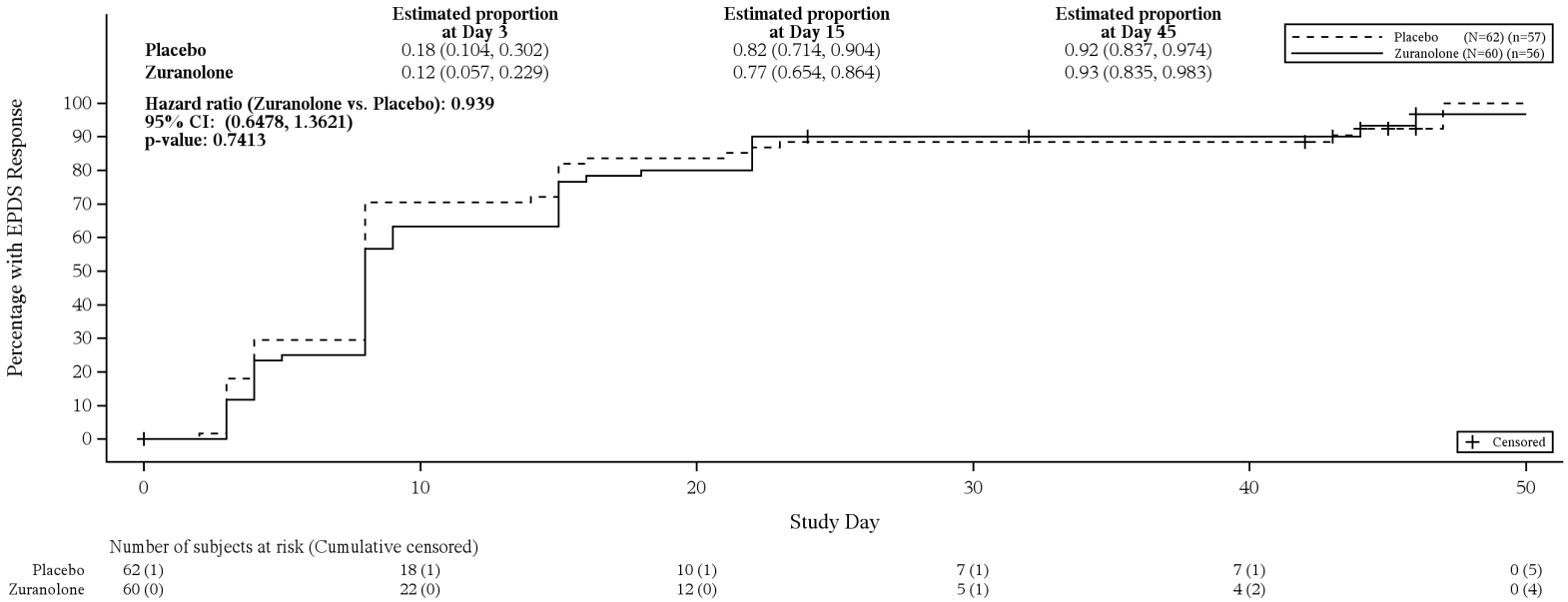
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Number of subjects at risk (Cumulative censored)

Placebo	62 (1)	18 (1)	10 (1)	7 (1)	7 (1)	0 (5)
Zuranolone	60 (0)	22 (0)	12 (0)	5 (1)	4 (2)	0 (4)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

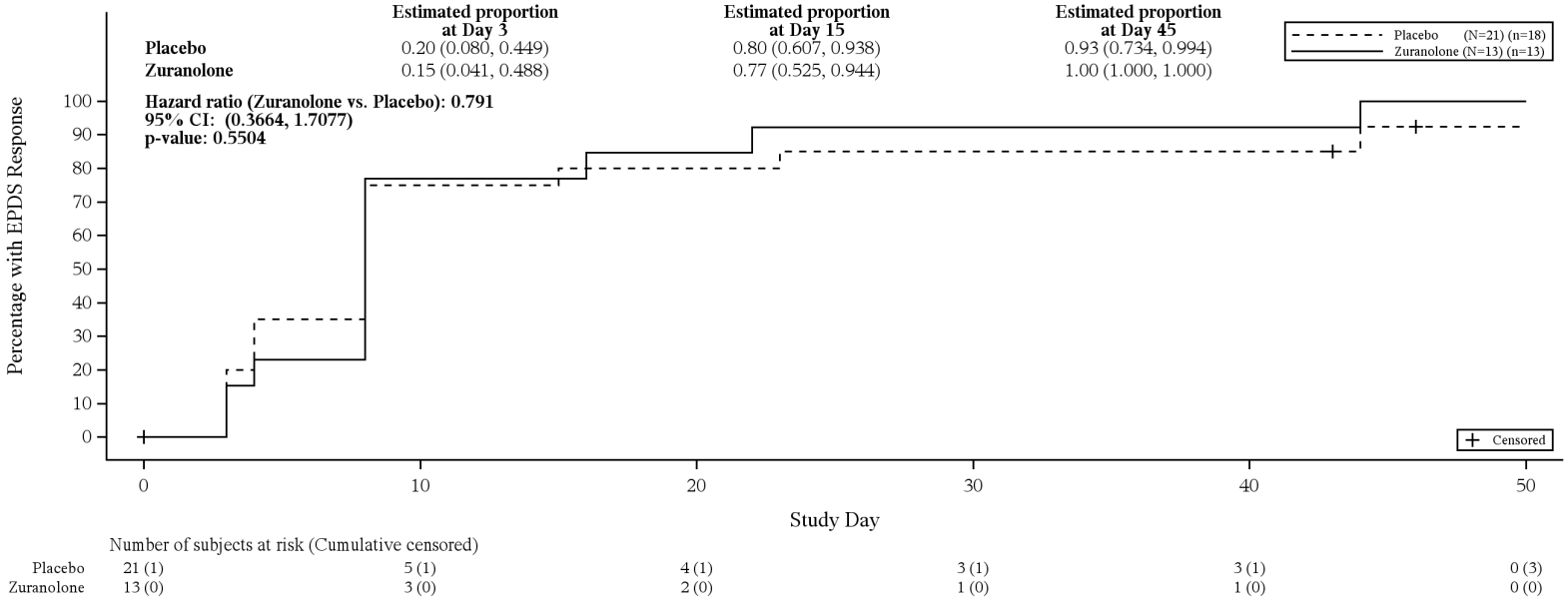
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Number of subjects at risk (Cumulative censored)

Placebo	21 (1)	5 (1)	4 (1)	3 (1)	3 (1)	0 (3)
Zuranolone	13 (0)	3 (0)	2 (0)	1 (0)	1 (0)	0 (0)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

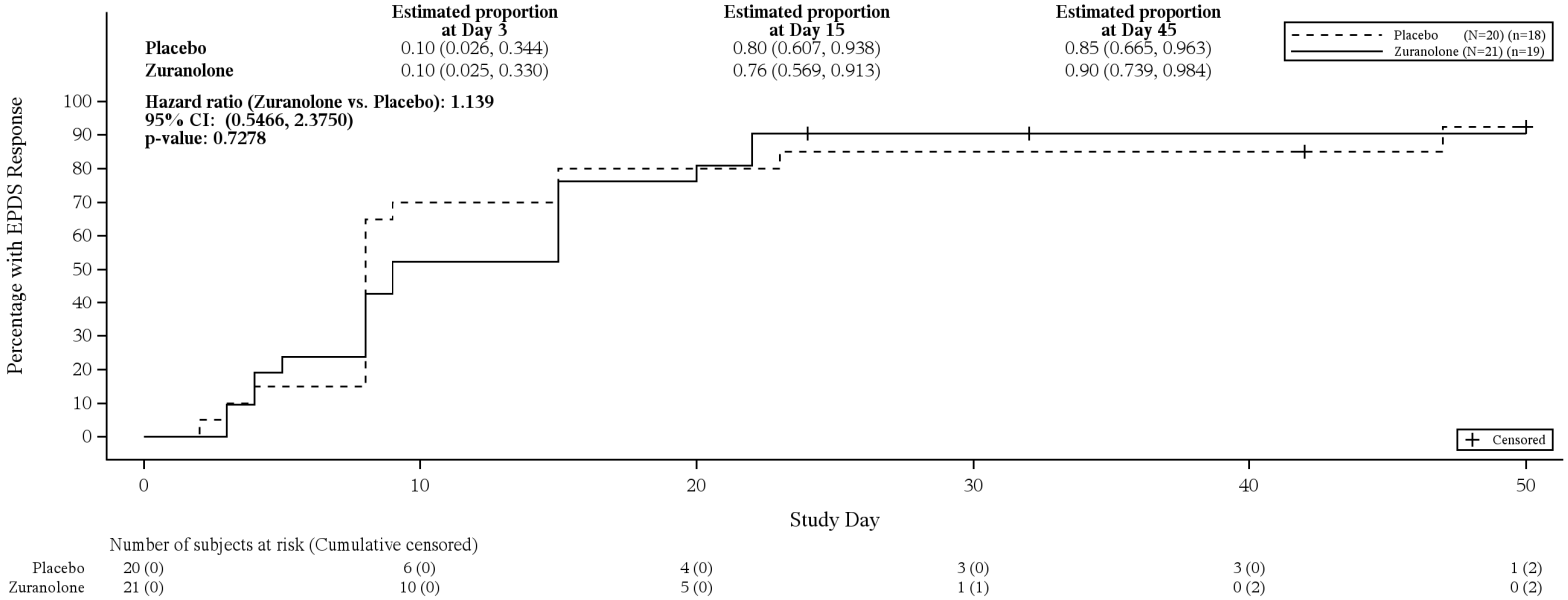
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Number of subjects at risk (Cumulative censored)

Placebo	20 (0)	6 (0)	4 (0)	3 (0)	3 (0)	1 (2)
Zuranolone	21 (0)	10 (0)	5 (0)	1 (1)	0 (2)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

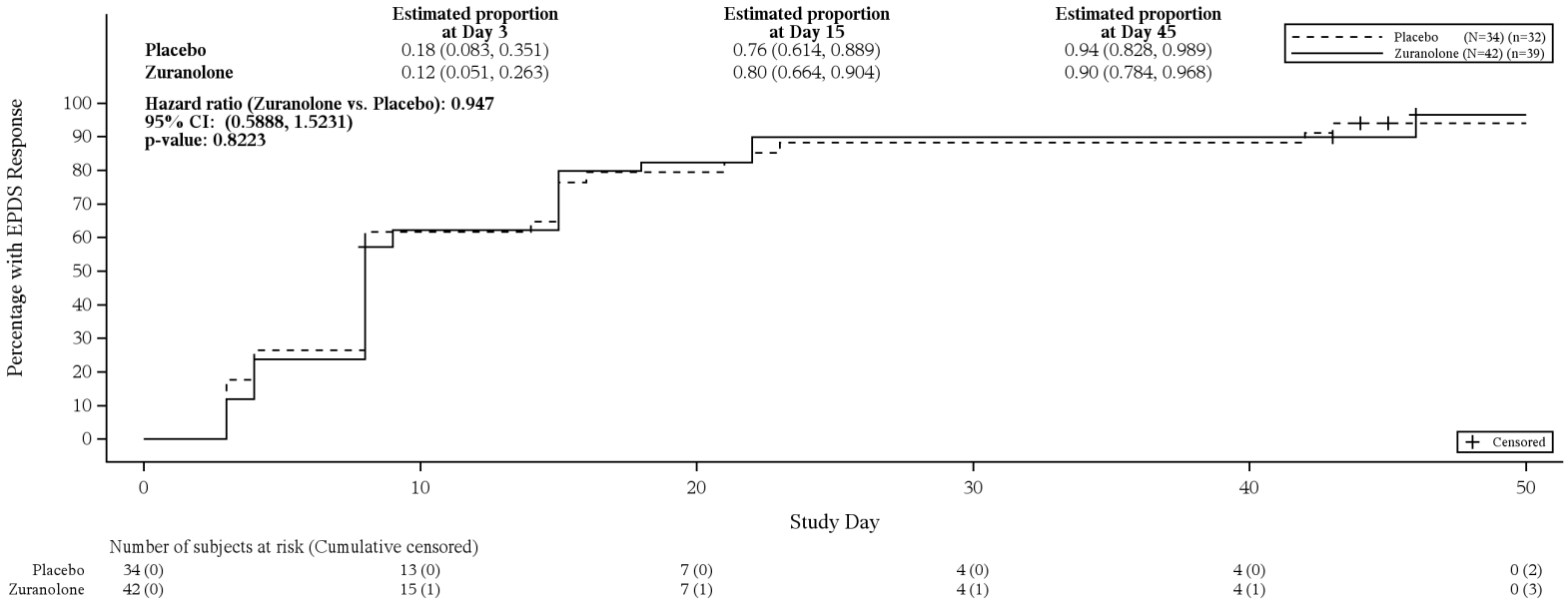
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Number of subjects at risk (Cumulative censored)

Placebo	34 (0)	13 (0)	7 (0)	4 (0)	4 (0)	0 (2)
Zuranolone	42 (0)	15 (1)	7 (1)	4 (1)	4 (1)	0 (3)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

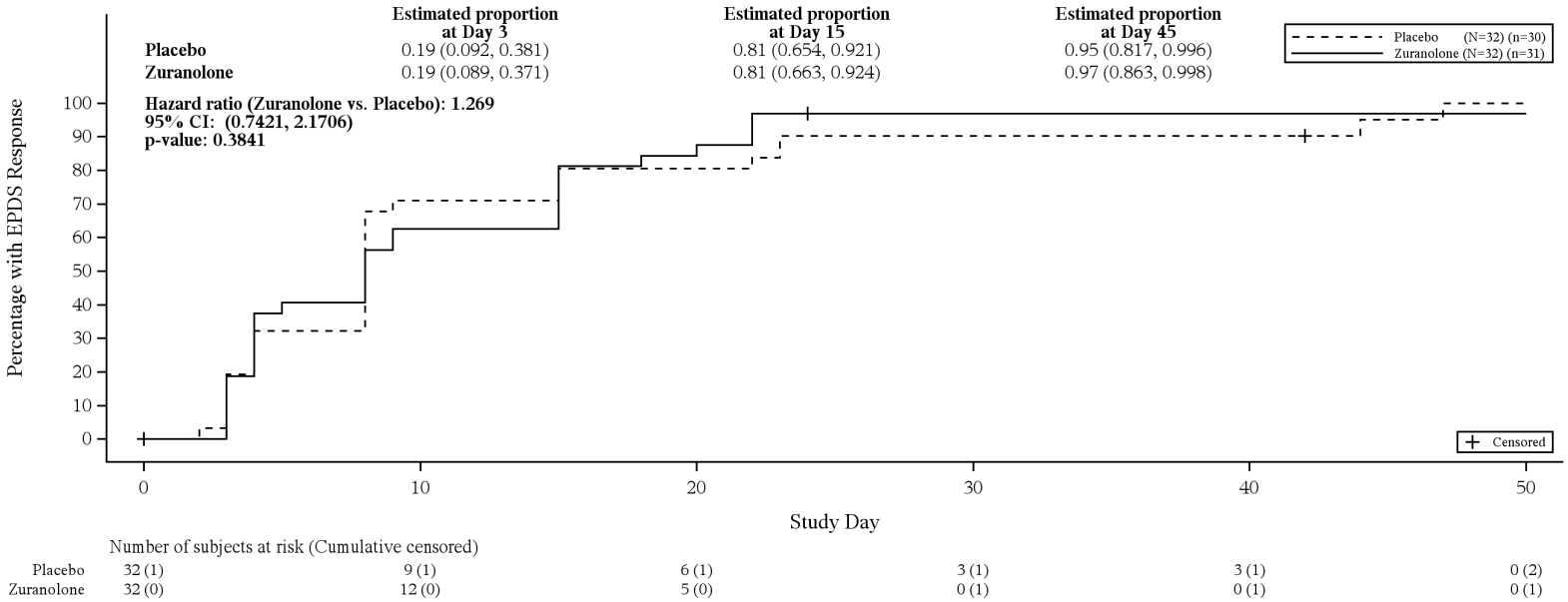
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Number of subjects at risk (Cumulative censored)

Placebo	32 (1)	9 (1)	6 (1)	3 (1)	3 (1)	0 (2)
Zuranolone	32 (0)	12 (0)	5 (0)	0 (1)	0 (1)	0 (1)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

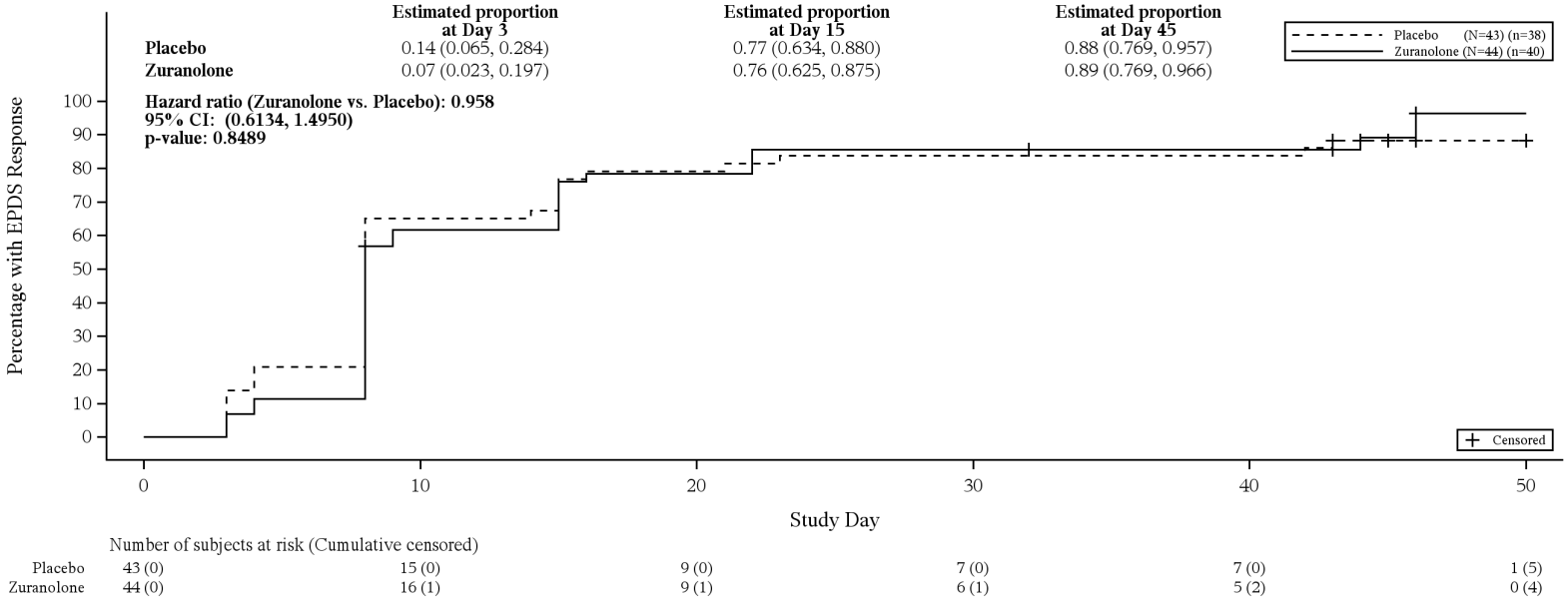
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

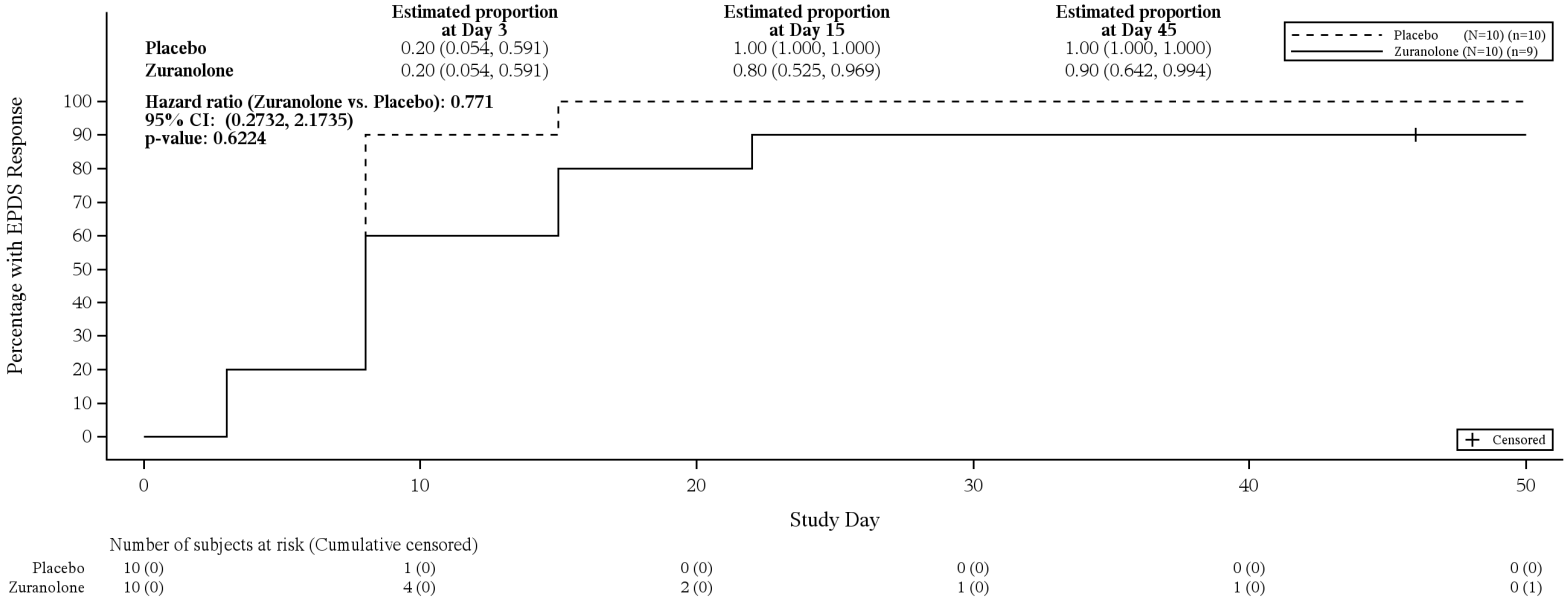
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

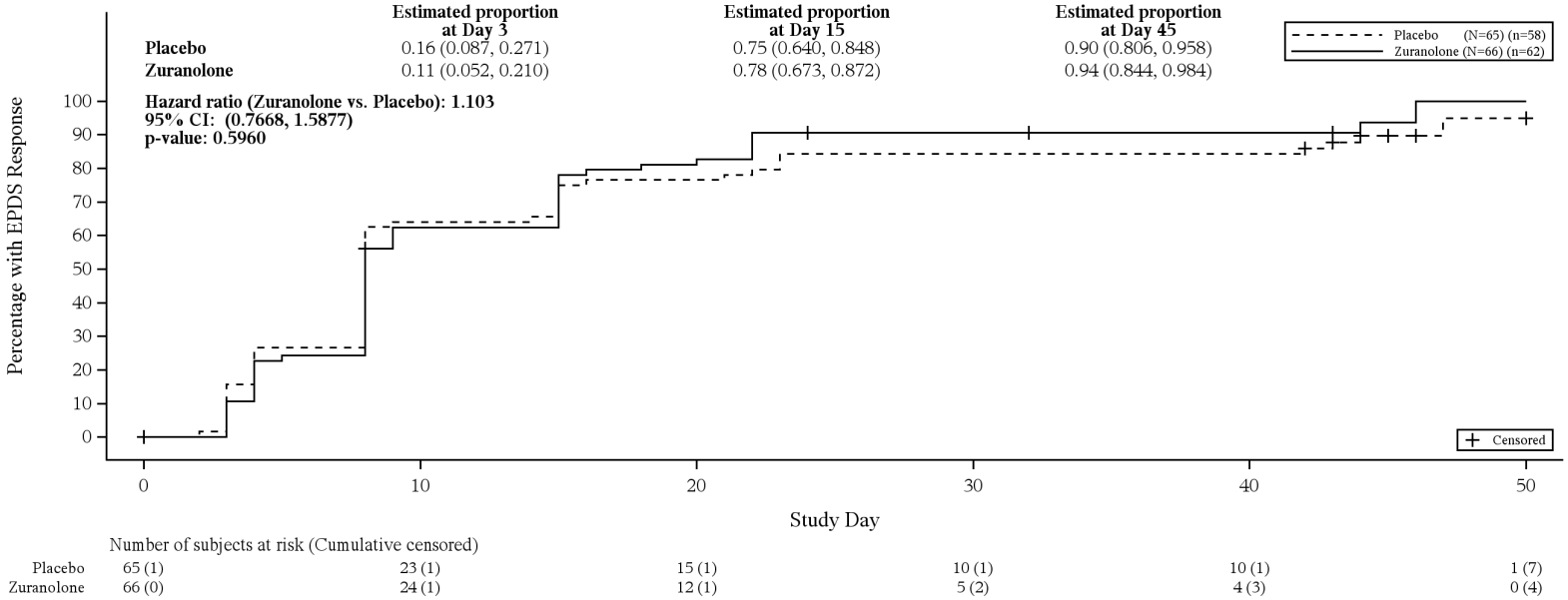
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

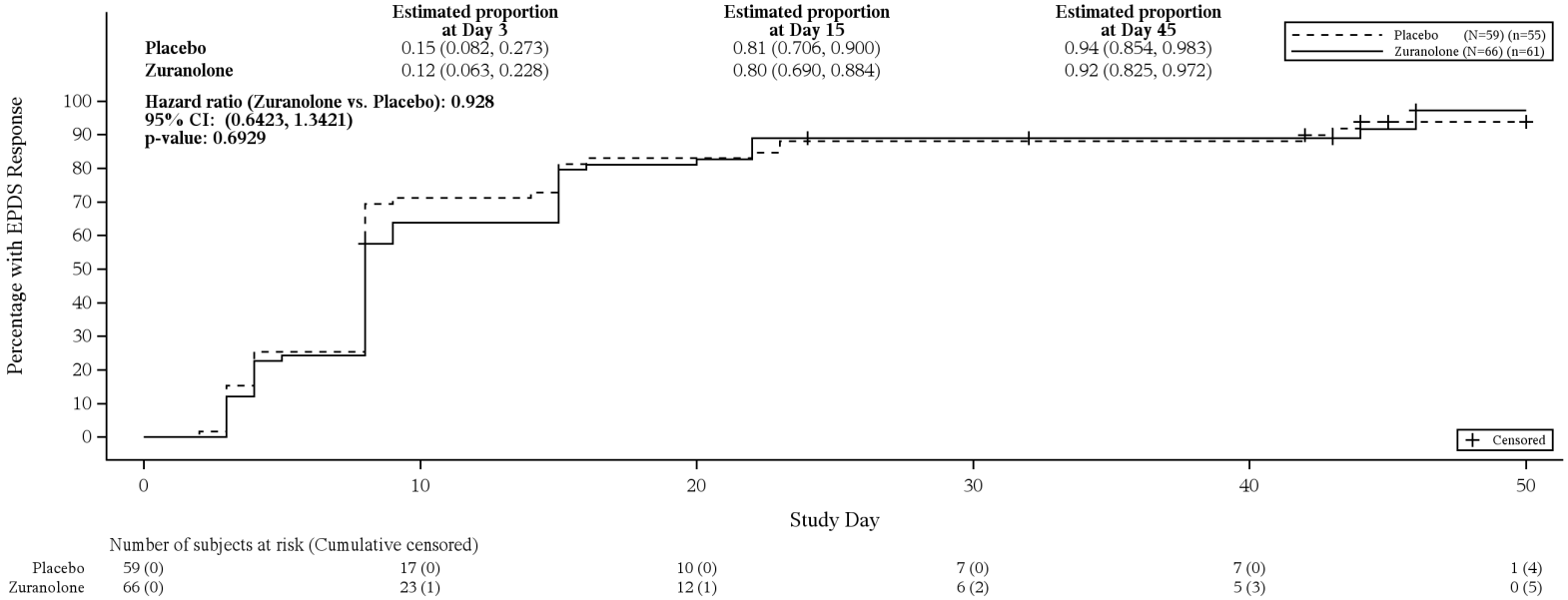
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

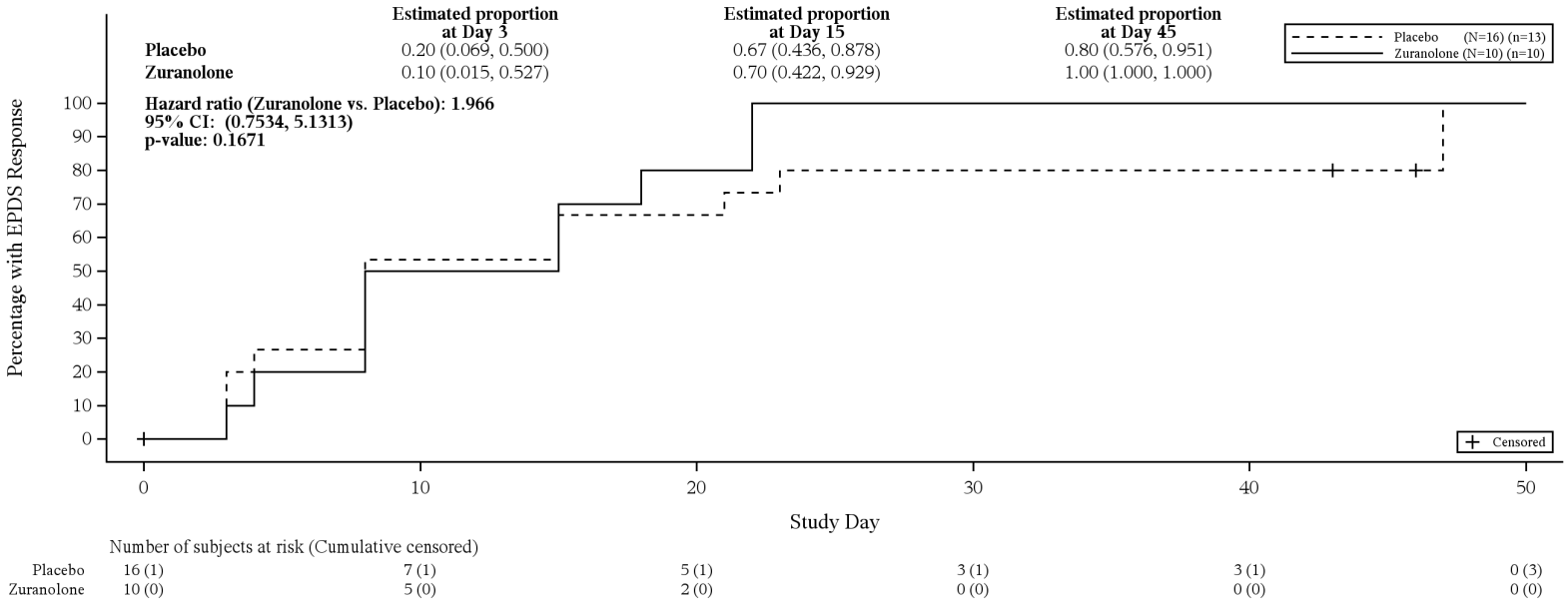
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

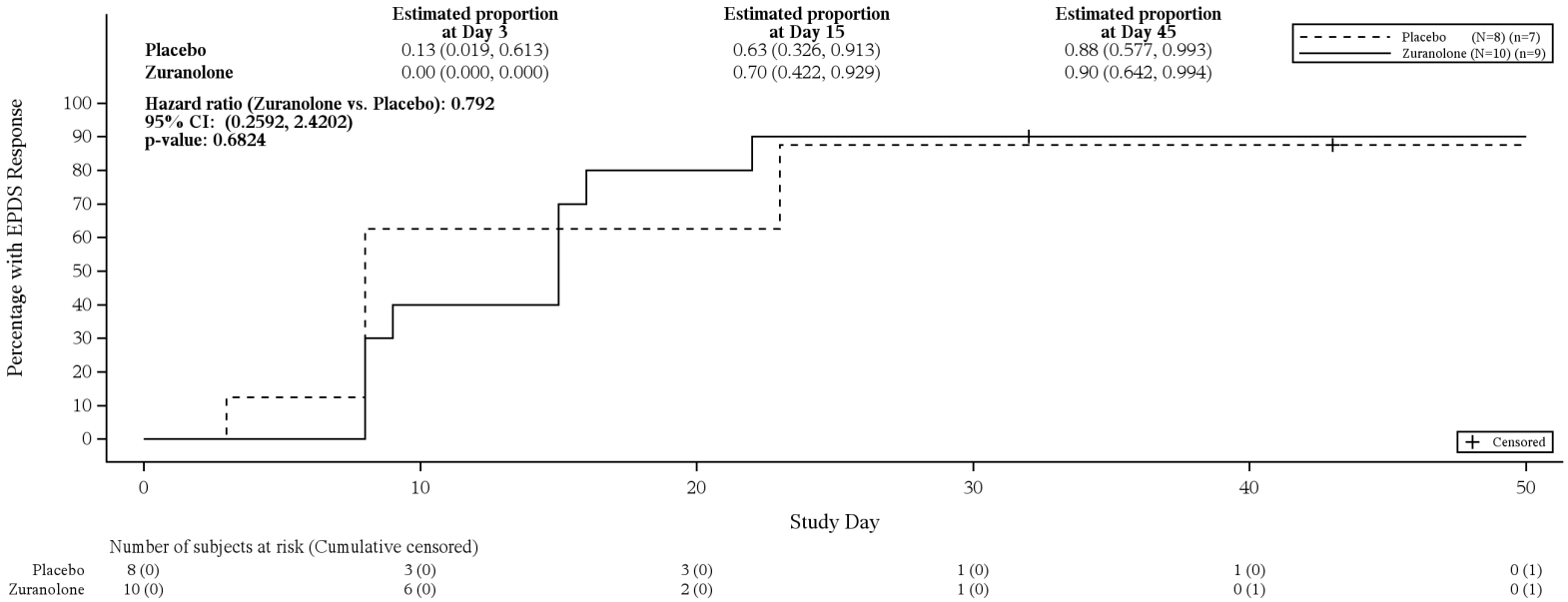
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20



Number of subjects at risk (Cumulative censored)

Placebo	8 (0)	3 (0)	3 (0)	1 (0)	1 (0)	0 (1)
Zuranolone	10 (0)	6 (0)	2 (0)	1 (0)	0 (1)	0 (1)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

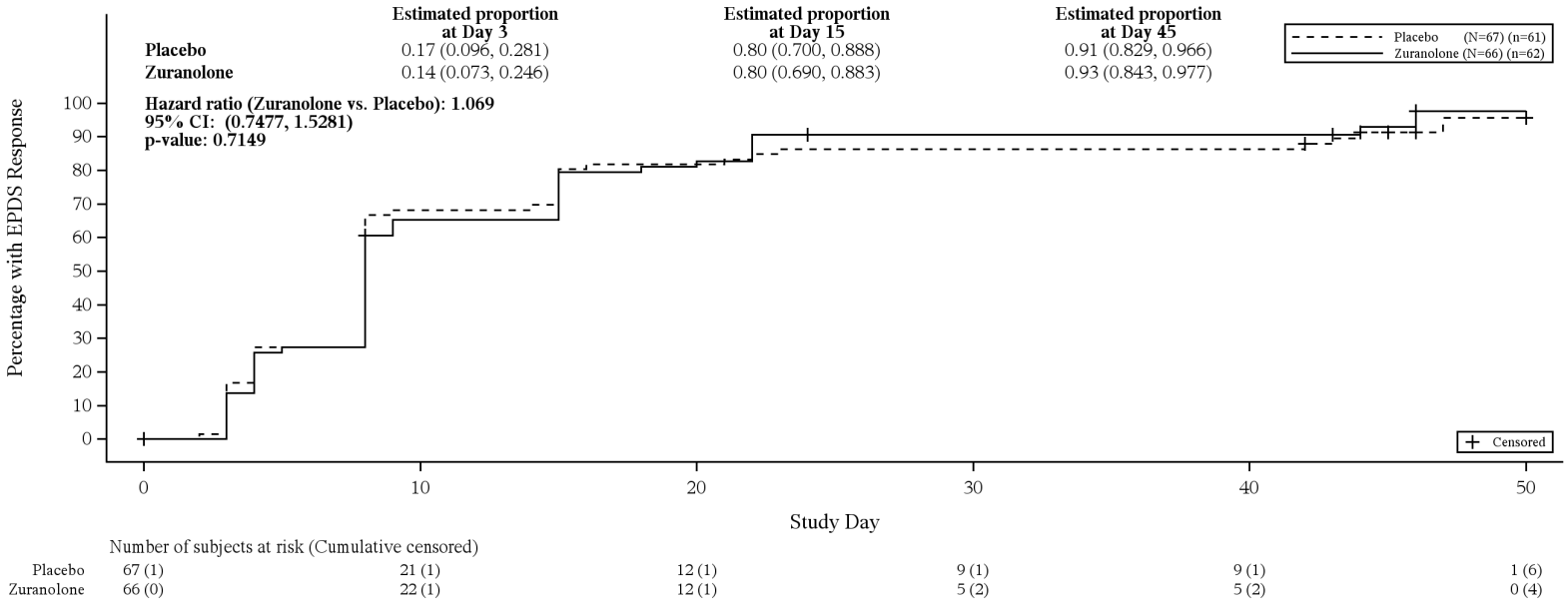
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-201-by.sas:f-epds-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: EPDS response is defined as 4.5 points (15% of total scale range 0-30) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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4.3.3 Verschlechterung

4.3.3.1 Responder-Analysen

4.3.3.1 .1 ITT-Population

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with worsening, n (%) [2]	2 (2.7)	0
Number of subjects with missing evaluation, n (%)	3 (4.0)	4 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.20
95% CI for the RR		(0.010, 4.044)
p-value for RR		0.2923
OR - Odds Ratio (Zuranolone vs. Placebo)		0.19
95% CI for the OR		(0.009, 4.070)
p-value for OR		0.2897
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.070, 0.018)
p-value for ARR		0.2388

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a EPDS worsening (4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-epds-wors15-201-ovr.sas:t-epds-wors15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 2 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with worsening, n (%) [2]	0	0
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a EPDS worsening (4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-epds-wors15-201-ovr.sas:t-epds-wors15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 3 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with worsening, n (%) [2]	0	0
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a EPDS worsening (4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-epds-wors15-201-ovr.sas:t-epds-wors15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 4 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with worsening, n (%) [2]	0	0
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a EPDS worsening (4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-epds-wors15-201-ovr.sas:t-epds-wors15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 5 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	0	0
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a EPDS worsening (4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-epds-wors15-201-ovr.sas:t-epds-wors15-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.3.3.1 .2 Subgruppen

4.3.3.1 .2 .1 Interaktionstest

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	0	0	
Number of subjects with response at Day 45, n (%)	0	0	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	0/25	0/17	
25 - 45, n / N (%)	0/50	0/59	
Day 45			
18 - 24, n / N (%)	0/25	0/17	
25 - 45, n / N (%)	0/50	0/59	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS worsening is defined as 4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-wors15-201-int.sas:t-epds-wors15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	0/22	0/30	
>=28, n / N (%)	0/53	0/46	
Day 45			
<28, n / N (%)	0/22	0/30	
>=28, n / N (%)	0/53	0/46	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	0/32	0/31	
White, n / N (%)	0/40	0/44	
Day 45			
Black or African American, n / N (%)	0/32	0/31	
White, n / N (%)	0/40	0/44	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS worsening is defined as 4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-wors15-201-int.sas:t-epds-wors15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	0/62	0/60	
Day 45			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	0/62	0/60	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS worsening is defined as 4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-wors15-201-int.sas:t-epds-wors15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	0/21	0/13	
25-29.9, n / N (%)	0/20	0/21	
>=30, n / N (%)	0/34	0/42	
Day 45			
<=24.9, n / N (%)	0/21	0/13	
25-29.9, n / N (%)	0/20	0/21	
>=30, n / N (%)	0/34	0/42	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS worsening is defined as 4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-wors15-201-int.sas:t-epds-wors15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 5 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	0/32	0/32	
Postpartum, n / N (%)	0/43	0/44	
Day 45			
3rd Trimester, n / N (%)	0/32	0/32	
Postpartum, n / N (%)	0/43	0/44	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	0/65	0/66	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	0/65	0/66	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS worsening is defined as 4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-wors15-201-int.sas:t-epds-wors15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 6 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	0/59	0/66	
Recurrent Episode, n / N (%)	0/16	0/10	
Day 45			
1st Episode, n / N (%)	0/59	0/66	
Recurrent Episode, n / N (%)	0/16	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	0/67	0/66	
Day 45			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	0/67	0/66	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS worsening is defined as 4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-wors15-201-int.sas:t-epds-wors15-201-int-itta.rtf **Run Date:** 30JUL2025

4.3.3.1 .2 .2 Subgruppenanalysen

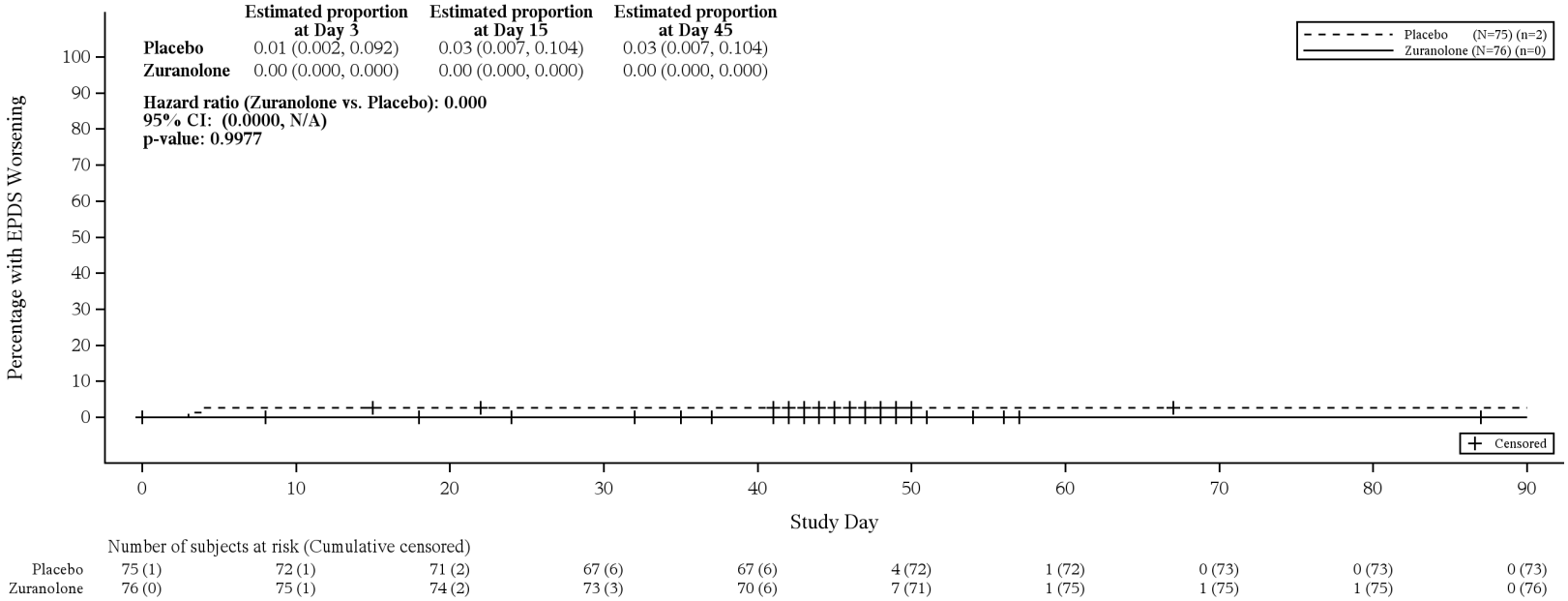
Nicht zutreffend.

4.3.3.2 TTE-Analysen

4.3.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing EPDS total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: EPDS worsening is defined as 4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-epds-wors15-tte-201-ovr.sas:f-epds-wors15-tte-201-ovr-itta.rtf **Run Date:** 16DEC2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	2 (2.7)	0
Time to first EPDS worsening (days) [3]		
25th percentile - Q1 (95% CI)	NE (NE, NE)	NE (NE, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.000
95% CI for the HR		(0.0000 , NE)
p-value for the HR		0.9977

NOTE 1: EPDS worsening is defined as 4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing EPDS total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a EPDS worsening. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline EPDS total score, and treatment.

Source: biib125/v_a/germany_amnog/t-epds-wors15-tte-201-ovr.sas:t-epds-wors15-tte-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.3.3.2 .2 Subgruppen

4.3.3.2 .2 .1 Interaktionstest

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	2 (2.7)	0	
Age Group (years)			
18 - 24, n / N (%)	1/25 (4.0)	0/17	NA
25 - 45, n / N (%)	1/50 (2.0)	0/59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	2/22 (9.1)	0/30	NA
>=28, n / N (%)	0/53	0/46	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	1/32 (3.1)	0/31	NA
White, n / N (%)	1/40 (2.5)	0/44	
Antidepressant Use at Baseline			
Yes, n / N (%)	0/13	0/16	NA
No, n / N (%)	2/62 (3.2)	0/60	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS worsening is defined as 4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-wors15-tte-201-int.sas:t-epds-wors15-tte-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	1/21 (4.8)	0/13	NA(a)
25-29.9, n / N (%)	1/20 (5.0)	0/21	NA(b)
>=30, n / N (%)	0/34	0/42	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	1/32 (3.1)	0/32	NA
Postpartum, n / N (%)	1/43 (2.3)	0/44	
Family History of PPD			
Yes, n / N (%)	0/10	0/10	NA
No/Unknown, n / N (%)	2/65 (3.1)	0/66	
History of PPD			
1st Episode, n / N (%)	0/59	0/66	NA
Recurrent Episode, n / N (%)	2/16 (12.5)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/8	0/10	NA
>=20, n / N (%)	2/67 (3.0)	0/66	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: EPDS worsening is defined as 4.5 points (15% of total scale range 0-30) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-epds-wors15-tte-201-int.sas:t-epds-wors15-tte-201-int-itta.rtf **Run Date:** 29JUL2025

4.3.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

4.3.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

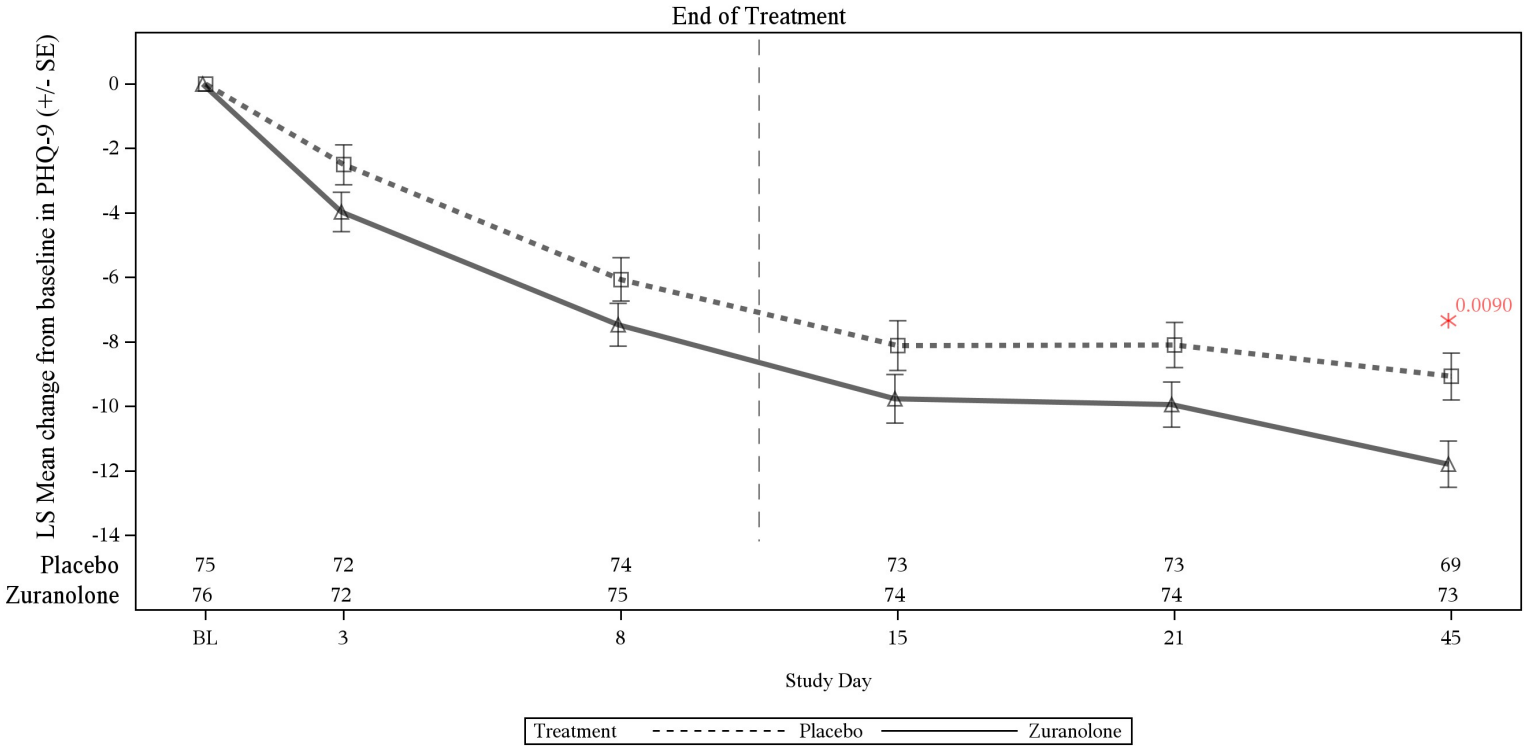
4.4 PHQ-9

4.4.1 MMRM

4.4.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time: 217-PPD-201B - ITT population

Page: 1 of 1



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-ovr.sas:f-phq9-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score: 217-PPD-201B - ITT population

Page: 1 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 3		
n	72	72
LS Mean (SE)	-2.50 (0.615)	-3.97 (0.613)
95% CI for the LS Mean	-3.71, -1.28	-5.19, -2.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.47 (0.868)
95% CI for the LS Mean		-3.19, 0.24
p-value		0.0918
Hedges' g (Zuranolone vs. Placebo)		-0.281
95% CI for Hedges' g		-0.6098, 0.0468
Day 8		
n	74	75
LS Mean (SE)	-6.06 (0.668)	-7.46 (0.663)
95% CI for the LS Mean	-7.39, -4.74	-8.77, -6.15
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.39 (0.941)
95% CI for the LS Mean		-3.25, 0.47
p-value		0.1409
Hedges' g (Zuranolone vs. Placebo)		-0.241
95% CI for Hedges' g		-0.5637, 0.0809

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-ovr.sas:t-phq9-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score: 217-PPD-201B - ITT population

Page: 2 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	-8.11 (0.767)	-9.76 (0.760)
95% CI for the LS Mean	-9.63, -6.59	-11.27, -8.26
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.65 (1.080)
95% CI for the LS Mean		-3.79, 0.48
p-value		0.1277
Hedges' g (Zuranolone vs. Placebo)		-0.251
95% CI for Hedges' g		-0.5760, 0.0731
Day 21		
n	73	74
LS Mean (SE)	-8.10 (0.700)	-9.94 (0.694)
95% CI for the LS Mean	-9.48, -6.71	-11.31, -8.57
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.84 (0.986)
95% CI for the LS Mean		-3.79, 0.10
p-value		0.0632
Hedges' g (Zuranolone vs. Placebo)		-0.307
95% CI for Hedges' g		-0.6324, 0.0180

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-ovr.sas:t-phq9-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score: 217-PPD-201B - ITT population

Page: 3 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 45		
n	69	73
LS Mean (SE)	-9.07 (0.734)	-11.79 (0.719)
95% CI for the LS Mean	-10.52, -7.62	-13.21, -10.37
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.72 (1.028)
95% CI for the LS Mean		-4.75, -0.69
p-value		0.0090
Hedges' g (Zuranolone vs. Placebo)		-0.442
95% CI for Hedges' g		-0.7754, -0.1092

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-ovr.sas:t-phq9-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.4.1.2 Subgruppen

4.4.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	25	17	0.9383
25 - 45	50	59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	22	30	0.3017
>=28	53	46	
Race Group (Black or African American, White)			
Black or African American	32	31	0.9356
White	40	44	
Antidepressant Use at Baseline			
Yes	13	16	0.1551
No	62	60	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-int.sas:t-phq9-mmrm-201-int-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score: Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	21	13	0.9064(a)
25-29.9	20	21	0.4084(b)
>=30	34	42	0.4495(c)
Onset of PPD			
3rd Trimester	32	32	0.8222
Postpartum	43	44	
Family History of PPD			
Yes	10	10	0.5353
No/Unknown	65	66	
History of PPD			
1st Episode	59	66	0.7392
Recurrent Episode	16	10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	8	10	NA
>=20	67	66	

NOTE 1: p-value is based on the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction as fixed effects with unstructured covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-int.sas:t-phq9-mmrm-201-int-itta.rtf **Run Date:** 29JUL2025

4.4.1.2 .2 Subgruppenanalysen

4.4.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Age Group: 217-PPD-201B - ITT population

Page: 1 of 6

Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Day 3		
n	25	16
LS Mean (SE)	-2.47 (1.127)	-2.55 (1.396)
95% CI for the LS Mean	-4.75, -0.19	-5.38, 0.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.08 (1.795)
95% CI for the LS Mean		-3.71, 3.55
p-value		0.9629
Hedges' g (Zuranolone vs. Placebo)		-0.015
95% CI for Hedges' g		-0.6422, 0.6128
Day 8		
n	25	17
LS Mean (SE)	-4.67 (1.114)	-6.45 (1.353)
95% CI for the LS Mean	-6.93, -2.42	-9.19, -3.72
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.78 (1.754)
95% CI for the LS Mean		-5.33, 1.77
p-value		0.3157
Hedges' g (Zuranolone vs. Placebo)		-0.314
95% CI for Hedges' g		-0.9333, 0.3062

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-age-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 15		
n	25	17
LS Mean (SE)	-6.43 (1.459)	-7.51 (1.771)
95% CI for the LS Mean	-9.38, -3.48	-11.09, -3.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.08 (2.295)
95% CI for the LS Mean		-5.72, 3.56
p-value		0.6400
Hedges' g (Zuranolone vs. Placebo)		-0.145
95% CI for Hedges' g		-0.7623, 0.4716
Day 21		
n	25	16
LS Mean (SE)	-6.59 (1.278)	-8.58 (1.576)
95% CI for the LS Mean	-9.18, -4.01	-11.76, -5.39
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.99 (2.030)
95% CI for the LS Mean		-6.09, 2.12
p-value		0.3338
Hedges' g (Zuranolone vs. Placebo)		-0.307
95% CI for Hedges' g		-0.9383, 0.3238

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-age-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Day 45		
n	25	16
LS Mean (SE)	-6.43 (1.339)	-10.27 (1.659)
95% CI for the LS Mean	-9.14, -3.72	-13.62, -6.91
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.84 (2.133)
95% CI for the LS Mean		-8.15, 0.48
p-value		0.0800
Hedges' g (Zuranolone vs. Placebo)		-0.564
95% CI for Hedges' g		-1.2037, 0.0749

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-age-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 3		
n	47	56
LS Mean (SE)	-2.43 (0.734)	-4.41 (0.673)
95% CI for the LS Mean	-3.88, -0.97	-5.75, -3.08
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.99 (0.997)
95% CI for the LS Mean		-3.96, -0.01
p-value		0.0492
Hedges' g (Zuranolone vs. Placebo)		-0.391
95% CI for Hedges' g		-0.7824, 0.0004
Day 8		
n	49	58
LS Mean (SE)	-6.72 (0.843)	-7.79 (0.773)
95% CI for the LS Mean	-8.39, -5.04	-9.33, -6.26
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.08 (1.145)
95% CI for the LS Mean		-3.35, 1.19
p-value		0.3493
Hedges' g (Zuranolone vs. Placebo)		-0.181
95% CI for Hedges' g		-0.5622, 0.1999

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-age-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 15		
n	48	57
LS Mean (SE)	-8.91 (0.916)	-10.48 (0.839)
95% CI for the LS Mean	-10.73, -7.09	-12.14, -8.81
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.57 (1.243)
95% CI for the LS Mean		-4.04, 0.90
p-value		0.2098
Hedges' g (Zuranolone vs. Placebo)		-0.245
95% CI for Hedges' g		-0.6309, 0.1399
Day 21		
n	48	58
LS Mean (SE)	-8.80 (0.847)	-10.41 (0.773)
95% CI for the LS Mean	-10.48, -7.12	-11.95, -8.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.62 (1.147)
95% CI for the LS Mean		-3.89, 0.66
p-value		0.1616
Hedges' g (Zuranolone vs. Placebo)		-0.273
95% CI for Hedges' g		-0.6573, 0.1111

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-age-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Day 45		
n	44	57
LS Mean (SE)	-10.43 (0.876)	-12.30 (0.783)
95% CI for the LS Mean	-12.17, -8.69	-13.85, -10.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.87 (1.176)
95% CI for the LS Mean		-4.20, 0.46
p-value		0.1154
Hedges' g (Zuranolone vs. Placebo)		-0.316
95% CI for Hedges' g		-0.7120, 0.0795

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.4.1.2 .2 .2 Schwere der Erkrankung

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 3		
n	20	26
LS Mean (SE)	-2.29 (1.036)	-3.38 (0.905)
95% CI for the LS Mean	-4.39, -0.20	-5.20, -1.55
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.08 (1.376)
95% CI for the LS Mean		-3.86, 1.70
p-value		0.4362
Hedges' g (Zuranolone vs. Placebo)		-0.230
95% CI for Hedges' g		-0.8146, 0.3550
Day 8		
n	22	29
LS Mean (SE)	-6.86 (1.210)	-7.24 (1.050)
95% CI for the LS Mean	-9.30, -4.43	-9.35, -5.13
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.38 (1.602)
95% CI for the LS Mean		-3.60, 2.84
p-value		0.8144
Hedges' g (Zuranolone vs. Placebo)		-0.066
95% CI for Hedges' g		-0.6200, 0.4886

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 15		
n	22	28
LS Mean (SE)	-9.41 (1.561)	-9.30 (1.358)
95% CI for the LS Mean	-12.55, -6.27	-12.04, -6.57
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.11 (2.069)
95% CI for the LS Mean		-4.06, 4.27
p-value		0.9595
Hedges' g (Zuranolone vs. Placebo)		0.014
95% CI for Hedges' g		-0.5441, 0.5727
Day 21		
n	22	28
LS Mean (SE)	-9.18 (1.370)	-9.09 (1.199)
95% CI for the LS Mean	-11.94, -6.42	-11.50, -6.68
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.09 (1.821)
95% CI for the LS Mean		-3.57, 3.76
p-value		0.9589
Hedges' g (Zuranolone vs. Placebo)		0.015
95% CI for Hedges' g		-0.5439, 0.5729

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Day 45		
n	22	28
LS Mean (SE)	-8.86 (1.448)	-11.08 (1.274)
95% CI for the LS Mean	-11.78, -5.95	-13.64, -8.52
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.22 (1.928)
95% CI for the LS Mean		-6.10, 1.66
p-value		0.2558
Hedges' g (Zuranolone vs. Placebo)		-0.323
95% CI for Hedges' g		-0.8845, 0.2394

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 3		
n	52	46
LS Mean (SE)	-2.56 (0.768)	-4.31 (0.817)
95% CI for the LS Mean	-4.08, -1.03	-5.94, -2.69
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.76 (1.122)
95% CI for the LS Mean		-3.98, 0.47
p-value		0.1209
Hedges' g (Zuranolone vs. Placebo)		-0.314
95% CI for Hedges' g		-0.7135, 0.0848
Day 8		
n	52	46
LS Mean (SE)	-5.73 (0.809)	-7.64 (0.861)
95% CI for the LS Mean	-7.34, -4.12	-9.35, -5.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.91 (1.182)
95% CI for the LS Mean		-4.26, 0.44
p-value		0.1096
Hedges' g (Zuranolone vs. Placebo)		-0.324
95% CI for Hedges' g		-0.7237, 0.0749

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 15		
n	51	46
LS Mean (SE)	-7.55 (0.866)	-10.05 (0.918)
95% CI for the LS Mean	-9.27, -5.83	-11.87, -8.23
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.50 (1.262)
95% CI for the LS Mean		-5.01, 0.00
p-value		0.0504
Hedges' g (Zuranolone vs. Placebo)		-0.400
95% CI for Hedges' g		-0.8022, 0.0027
Day 21		
n	51	46
LS Mean (SE)	-7.64 (0.809)	-10.47 (0.857)
95% CI for the LS Mean	-9.25, -6.04	-12.17, -8.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.82 (1.179)
95% CI for the LS Mean		-5.16, -0.48
p-value		0.0186
Hedges' g (Zuranolone vs. Placebo)		-0.483
95% CI for Hedges' g		-0.8872, -0.0786

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Day 45		
n	47	45
LS Mean (SE)	-9.22 (0.848)	-12.20 (0.883)
95% CI for the LS Mean	-10.90, -7.53	-13.95, -10.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.98 (1.225)
95% CI for the LS Mean		-5.42, -0.55
p-value		0.0168
Hedges' g (Zuranolone vs. Placebo)		-0.503
95% CI for Hedges' g		-0.9186, -0.0882

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.4.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 3		
n	31	29
LS Mean (SE)	-2.88 (0.982)	-3.94 (1.004)
95% CI for the LS Mean	-4.84, -0.91	-5.95, -1.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.06 (1.405)
95% CI for the LS Mean		-3.88, 1.75
p-value		0.4516
Hedges' g (Zuranolone vs. Placebo)		-0.193
95% CI for Hedges' g		-0.7008, 0.3142
Day 8		
n	31	31
LS Mean (SE)	-7.13 (1.073)	-8.46 (1.073)
95% CI for the LS Mean	-9.28, -4.99	-10.61, -6.31
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.33 (1.519)
95% CI for the LS Mean		-4.37, 1.71
p-value		0.3851
Hedges' g (Zuranolone vs. Placebo)		-0.219
95% CI for Hedges' g		-0.7188, 0.2799

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-race-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 15		
n	31	31
LS Mean (SE)	-8.39 (1.198)	-10.46 (1.198)
95% CI for the LS Mean	-10.79, -5.99	-12.86, -8.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.07 (1.696)
95% CI for the LS Mean		-5.46, 1.32
p-value		0.2268
Hedges' g (Zuranolone vs. Placebo)		-0.306
95% CI for Hedges' g		-0.8071, 0.1944
Day 21		
n	31	30
LS Mean (SE)	-8.62 (1.115)	-9.90 (1.126)
95% CI for the LS Mean	-10.85, -6.38	-12.15, -7.64
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.28 (1.586)
95% CI for the LS Mean		-4.46, 1.90
p-value		0.4225
Hedges' g (Zuranolone vs. Placebo)		-0.204
95% CI for Hedges' g		-0.7075, 0.2990

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-race-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Day 45		
n	30	30
LS Mean (SE)	-9.37 (1.075)	-12.27 (1.078)
95% CI for the LS Mean	-11.52, -7.22	-14.43, -10.11
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.90 (1.524)
95% CI for the LS Mean		-5.95, 0.15
p-value		0.0617
Hedges' g (Zuranolone vs. Placebo)		-0.485
95% CI for Hedges' g		-0.9988, 0.0281

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-race-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 3		
n	39	42
LS Mean (SE)	-2.47 (0.791)	-3.72 (0.761)
95% CI for the LS Mean	-4.04, -0.89	-5.24, -2.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.25 (1.098)
95% CI for the LS Mean		-3.44, 0.93
p-value		0.2569
Hedges' g (Zuranolone vs. Placebo)		-0.252
95% CI for Hedges' g		-0.6892, 0.1860
Day 8		
n	40	43
LS Mean (SE)	-5.31 (0.872)	-6.57 (0.838)
95% CI for the LS Mean	-7.05, -3.58	-8.24, -4.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.26 (1.209)
95% CI for the LS Mean		-3.66, 1.15
p-value		0.3024
Hedges' g (Zuranolone vs. Placebo)		-0.226
95% CI for Hedges' g		-0.6579, 0.2060

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-race-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 15		
n	39	42
LS Mean (SE)	-7.90 (1.056)	-9.19 (1.015)
95% CI for the LS Mean	-10.01, -5.80	-11.21, -7.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.28 (1.465)
95% CI for the LS Mean		-4.20, 1.63
p-value		0.3834
Hedges' g (Zuranolone vs. Placebo)		-0.193
95% CI for Hedges' g		-0.6300, 0.2437
Day 21		
n	39	43
LS Mean (SE)	-7.70 (0.926)	-10.19 (0.886)
95% CI for the LS Mean	-9.54, -5.86	-11.95, -8.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.49 (1.281)
95% CI for the LS Mean		-5.04, 0.06
p-value		0.0554
Hedges' g (Zuranolone vs. Placebo)		-0.426
95% CI for Hedges' g		-0.8643, 0.0123

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-race-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Day 45		
n	36	42
LS Mean (SE)	-9.03 (1.044)	-11.34 (0.984)
95% CI for the LS Mean	-11.11, -6.95	-13.30, -9.38
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.31 (1.435)
95% CI for the LS Mean		-5.17, 0.55
p-value		0.1113
Hedges' g (Zuranolone vs. Placebo)		-0.362
95% CI for Hedges' g		-0.8110, 0.0865

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.4.1.2 .2 .4 Antidepressiva-Nutzung

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 3		
n	13	14
LS Mean (SE)	-0.82 (0.918)	-4.25 (0.889)
95% CI for the LS Mean	-2.74, 1.09	-6.10, -2.41
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.43 (1.287)
95% CI for the LS Mean		-6.11, -0.75
p-value		0.0145
Hedges' g (Zuranolone vs. Placebo)		-0.996
95% CI for Hedges' g		-1.7963, -0.1957
Day 8		
n	13	16
LS Mean (SE)	-4.98 (1.483)	-7.92 (1.338)
95% CI for the LS Mean	-8.03, -1.93	-10.67, -5.17
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.94 (2.002)
95% CI for the LS Mean		-7.06, 1.17
p-value		0.1534
Hedges' g (Zuranolone vs. Placebo)		-0.534
95% CI for Hedges' g		-1.2783, 0.2109

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 15		
n	13	15
LS Mean (SE)	-7.28 (1.988)	-12.00 (1.830)
95% CI for the LS Mean	-11.38, -3.19	-15.77, -8.24
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.72 (2.705)
95% CI for the LS Mean		-10.29, 0.85
p-value		0.0934
Hedges' g (Zuranolone vs. Placebo)		-0.642
95% CI for Hedges' g		-1.4030, 0.1199
Day 21		
n	12	15
LS Mean (SE)	-7.59 (1.631)	-11.15 (1.480)
95% CI for the LS Mean	-10.94, -4.23	-14.19, -8.11
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.57 (2.207)
95% CI for the LS Mean		-8.10, 0.97
p-value		0.1182
Hedges' g (Zuranolone vs. Placebo)		-0.607
95% CI for Hedges' g		-1.3828, 0.1695

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Day 45		
n	11	15
LS Mean (SE)	-10.17 (1.734)	-13.29 (1.544)
95% CI for the LS Mean	-13.73, -6.60	-16.47, -10.10
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.12 (2.327)
95% CI for the LS Mean		-7.91, 1.67
p-value		0.1915
Hedges' g (Zuranolone vs. Placebo)		-0.516
95% CI for Hedges' g		-1.3064, 0.2747

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 3		
n	59	58
LS Mean (SE)	-2.93 (0.705)	-3.77 (0.712)
95% CI for the LS Mean	-4.32, -1.53	-5.18, -2.36
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.84 (1.002)
95% CI for the LS Mean		-2.83, 1.14
p-value		0.4020
Hedges' g (Zuranolone vs. Placebo)		-0.155
95% CI for Hedges' g		-0.5175, 0.2084
Day 8		
n	61	59
LS Mean (SE)	-6.35 (0.751)	-7.26 (0.762)
95% CI for the LS Mean	-7.84, -4.86	-8.77, -5.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.91 (1.070)
95% CI for the LS Mean		-3.03, 1.20
p-value		0.3942
Hedges' g (Zuranolone vs. Placebo)		-0.155
95% CI for Hedges' g		-0.5136, 0.2033

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 15		
n	60	59
LS Mean (SE)	-8.34 (0.837)	-9.13 (0.844)
95% CI for the LS Mean	-9.99, -6.68	-10.80, -7.46
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.79 (1.189)
95% CI for the LS Mean		-3.15, 1.56
p-value		0.5067
Hedges' g (Zuranolone vs. Placebo)		-0.121
95% CI for Hedges' g		-0.4810, 0.2384
Day 21		
n	61	59
LS Mean (SE)	-8.27 (0.780)	-9.56 (0.789)
95% CI for the LS Mean	-9.81, -6.72	-11.12, -8.00
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.29 (1.110)
95% CI for the LS Mean		-3.49, 0.90
p-value		0.2465
Hedges' g (Zuranolone vs. Placebo)		-0.211
95% CI for Hedges' g		-0.5702, 0.1476

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Day 45		
n	58	58
LS Mean (SE)	-8.92 (0.816)	-11.34 (0.820)
95% CI for the LS Mean	-10.53, -7.30	-12.96, -9.72
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.42 (1.157)
95% CI for the LS Mean		-4.71, -0.13
p-value		0.0385
Hedges' g (Zuranolone vs. Placebo)		-0.386
95% CI for Hedges' g		-0.7535, -0.0189

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.4.1.2 .2 .5 BMI

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 3		
n	20	13
LS Mean (SE)	-3.31 (1.078)	-2.71 (1.337)
95% CI for the LS Mean	-5.51, -1.10	-5.44, 0.03
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.60 (1.718)
95% CI for the LS Mean		-2.92, 4.11
p-value		0.7308
Hedges' g (Zuranolone vs. Placebo)		0.121
95% CI for Hedges' g		-0.5781, 0.8196
Day 8		
n	20	13
LS Mean (SE)	-6.06 (1.277)	-7.17 (1.585)
95% CI for the LS Mean	-8.66, -3.45	-10.40, -3.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.11 (2.036)
95% CI for the LS Mean		-5.27, 3.04
p-value		0.5881
Hedges' g (Zuranolone vs. Placebo)		-0.190
95% CI for Hedges' g		-0.8900, 0.5095

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 15		
n	20	13
LS Mean (SE)	-6.51 (1.516)	-9.86 (1.880)
95% CI for the LS Mean	-9.61, -3.40	-13.71, -6.01
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.36 (2.416)
95% CI for the LS Mean		-8.30, 1.59
p-value		0.1755
Hedges' g (Zuranolone vs. Placebo)		-0.483
95% CI for Hedges' g		-1.1908, 0.2250
Day 21		
n	19	12
LS Mean (SE)	-7.03 (1.325)	-12.37 (1.656)
95% CI for the LS Mean	-9.75, -4.31	-15.77, -8.97
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-5.34 (2.122)
95% CI for the LS Mean		-9.69, -0.98
p-value		0.0181
Hedges' g (Zuranolone vs. Placebo)		-0.904
95% CI for Hedges' g		-1.6604, -0.1466

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Day 45		
n	18	12
LS Mean (SE)	-7.58 (1.559)	-12.28 (1.923)
95% CI for the LS Mean	-10.78, -4.39	-16.22, -8.34
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.70 (2.476)
95% CI for the LS Mean		-9.77, 0.38
p-value		0.0682
Hedges' g (Zuranolone vs. Placebo)		-0.687
95% CI for Hedges' g		-1.4383, 0.0634

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 3		
n	19	20
LS Mean (SE)	-2.31 (1.369)	-5.65 (1.342)
95% CI for the LS Mean	-5.09, 0.48	-8.38, -2.92
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.35 (1.935)
95% CI for the LS Mean		-7.28, 0.59
p-value		0.0930
Hedges' g (Zuranolone vs. Placebo)		-0.543
95% CI for Hedges' g		-1.1821, 0.0966
Day 8		
n	20	20
LS Mean (SE)	-6.10 (1.441)	-9.63 (1.418)
95% CI for the LS Mean	-9.02, -3.17	-12.50, -6.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.53 (2.037)
95% CI for the LS Mean		-7.66, 0.60
p-value		0.0916
Hedges' g (Zuranolone vs. Placebo)		-0.537
95% CI for Hedges' g		-1.1680, 0.0937

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 15		
n	20	20
LS Mean (SE)	-8.80 (1.658)	-10.48 (1.626)
95% CI for the LS Mean	-12.16, -5.43	-13.78, -7.18
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.68 (2.335)
95% CI for the LS Mean		-6.42, 3.05
p-value		0.4754
Hedges' g (Zuranolone vs. Placebo)		-0.224
95% CI for Hedges' g		-0.8453, 0.3982
Day 21		
n	20	21
LS Mean (SE)	-8.75 (1.620)	-11.04 (1.576)
95% CI for the LS Mean	-12.03, -5.47	-14.23, -7.85
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.29 (2.273)
95% CI for the LS Mean		-6.89, 2.31
p-value		0.3190
Hedges' g (Zuranolone vs. Placebo)		-0.309
95% CI for Hedges' g		-0.9253, 0.3067

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Day 45		
n	20	20
LS Mean (SE)	-10.80 (1.467)	-13.06 (1.442)
95% CI for the LS Mean	-13.78, -7.82	-15.99, -10.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.26 (2.072)
95% CI for the LS Mean		-6.47, 1.94
p-value		0.2820
Hedges' g (Zuranolone vs. Placebo)		-0.339
95% CI for Hedges' g		-0.9629, 0.2856

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 3		
n	33	39
LS Mean (SE)	-1.99 (0.884)	-3.54 (0.811)
95% CI for the LS Mean	-3.75, -0.22	-5.16, -1.92
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.55 (1.201)
95% CI for the LS Mean		-3.95, 0.84
p-value		0.2003
Hedges' g (Zuranolone vs. Placebo)		-0.303
95% CI for Hedges' g		-0.7688, 0.1636
Day 8		
n	34	42
LS Mean (SE)	-5.99 (0.951)	-6.48 (0.856)
95% CI for the LS Mean	-7.89, -4.10	-8.18, -4.77
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.49 (1.280)
95% CI for the LS Mean		-3.04, 2.06
p-value		0.7053
Hedges' g (Zuranolone vs. Placebo)		-0.087
95% CI for Hedges' g		-0.5390, 0.3657

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 15		
n	33	41
LS Mean (SE)	-8.60 (1.095)	-9.40 (0.987)
95% CI for the LS Mean	-10.78, -6.42	-11.37, -7.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.80 (1.475)
95% CI for the LS Mean		-3.74, 2.14
p-value		0.5873
Hedges' g (Zuranolone vs. Placebo)		-0.126
95% CI for Hedges' g		-0.5850, 0.3327
Day 21		
n	34	41
LS Mean (SE)	-8.23 (0.936)	-8.69 (0.851)
95% CI for the LS Mean	-10.09, -6.36	-10.39, -7.00
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.47 (1.266)
95% CI for the LS Mean		-2.99, 2.06
p-value		0.7135
Hedges' g (Zuranolone vs. Placebo)		-0.085
95% CI for Hedges' g		-0.5394, 0.3702

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Day 45		
n	31	41
LS Mean (SE)	-8.71 (1.060)	-10.98 (0.933)
95% CI for the LS Mean	-10.82, -6.60	-12.84, -9.13
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.27 (1.413)
95% CI for the LS Mean		-5.09, 0.54
p-value		0.1121
Hedges' g (Zuranolone vs. Placebo)		-0.379
95% CI for Hedges' g		-0.8493, 0.0919

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.4.1.2 .2 .6 Beginn der PPD

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 3		
n	31	32
LS Mean (SE)	-3.61 (1.049)	-5.52 (1.032)
95% CI for the LS Mean	-5.71, -1.52	-7.59, -3.46
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.91 (1.473)
95% CI for the LS Mean		-4.85, 1.04
p-value		0.2001
Hedges' g (Zuranolone vs. Placebo)		-0.322
95% CI for Hedges' g		-0.8196, 0.1746
Day 8		
n	31	32
LS Mean (SE)	-6.74 (1.133)	-8.05 (1.115)
95% CI for the LS Mean	-9.01, -4.48	-10.28, -5.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.31 (1.591)
95% CI for the LS Mean		-4.49, 1.87
p-value		0.4132
Hedges' g (Zuranolone vs. Placebo)		-0.205
95% CI for Hedges' g		-0.7003, 0.2901

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 15		
n	31	32
LS Mean (SE)	-7.90 (1.207)	-9.34 (1.188)
95% CI for the LS Mean	-10.32, -5.49	-11.71, -6.96
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.43 (1.694)
95% CI for the LS Mean		-4.82, 1.96
p-value		0.4017
Hedges' g (Zuranolone vs. Placebo)		-0.210
95% CI for Hedges' g		-0.7055, 0.2851
Day 21		
n	30	31
LS Mean (SE)	-8.05 (1.118)	-10.16 (1.100)
95% CI for the LS Mean	-10.29, -5.81	-12.36, -7.96
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.11 (1.569)
95% CI for the LS Mean		-5.25, 1.03
p-value		0.1831
Hedges' g (Zuranolone vs. Placebo)		-0.341
95% CI for Hedges' g		-0.8462, 0.1650

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Day 45		
n	29	30
LS Mean (SE)	-9.22 (1.130)	-12.64 (1.111)
95% CI for the LS Mean	-11.48, -6.96	-14.86, -10.41
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.41 (1.586)
95% CI for the LS Mean		-6.59, -0.24
p-value		0.0356
Hedges' g (Zuranolone vs. Placebo)		-0.553
95% CI for Hedges' g		-1.0731, -0.0330

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 3		
n	41	40
LS Mean (SE)	-1.69 (0.724)	-2.84 (0.731)
95% CI for the LS Mean	-3.13, -0.25	-4.30, -1.39
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.15 (1.030)
95% CI for the LS Mean		-3.21, 0.90
p-value		0.2658
Hedges' g (Zuranolone vs. Placebo)		-0.247
95% CI for Hedges' g		-0.6840, 0.1905
Day 8		
n	43	43
LS Mean (SE)	-5.56 (0.826)	-7.03 (0.824)
95% CI for the LS Mean	-7.21, -3.92	-8.67, -5.40
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.47 (1.168)
95% CI for the LS Mean		-3.80, 0.85
p-value		0.2114
Hedges' g (Zuranolone vs. Placebo)		-0.269
95% CI for Hedges' g		-0.6938, 0.1554

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 15		
n	42	42
LS Mean (SE)	-8.25 (1.009)	-10.09 (1.005)
95% CI for the LS Mean	-10.25, -6.24	-12.09, -8.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.85 (1.425)
95% CI for the LS Mean		-4.69, 0.99
p-value		0.1983
Hedges' g (Zuranolone vs. Placebo)		-0.280
95% CI for Hedges' g		-0.7103, 0.1493
Day 21		
n	43	43
LS Mean (SE)	-8.12 (0.915)	-9.80 (0.912)
95% CI for the LS Mean	-9.94, -6.30	-11.62, -7.99
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.68 (1.293)
95% CI for the LS Mean		-4.25, 0.89
p-value		0.1972
Hedges' g (Zuranolone vs. Placebo)		-0.278
95% CI for Hedges' g		-0.7025, 0.1469

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Day 45		
n	40	43
LS Mean (SE)	-8.99 (0.977)	-11.27 (0.958)
95% CI for the LS Mean	-10.93, -7.04	-13.17, -9.36
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.28 (1.370)
95% CI for the LS Mean		-5.01, 0.44
p-value		0.0997
Hedges' g (Zuranolone vs. Placebo)		-0.362
95% CI for Hedges' g		-0.7965, 0.0716

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.4.1.2 .2 .7 PPD in der Familie

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 3		
n	10	10
LS Mean (SE)	-2.79 (1.413)	-3.69 (1.415)
95% CI for the LS Mean	-5.77, 0.20	-6.68, -0.70
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.90 (2.046)
95% CI for the LS Mean		-5.21, 3.41
p-value		0.6639
Hedges' g (Zuranolone vs. Placebo)		-0.189
95% CI for Hedges' g		-1.0678, 0.6891
Day 8		
n	10	10
LS Mean (SE)	-5.99 (1.489)	-5.29 (1.492)
95% CI for the LS Mean	-9.12, -2.85	-8.43, -2.15
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.70 (2.152)
95% CI for the LS Mean		-3.83, 5.22
p-value		0.7502
Hedges' g (Zuranolone vs. Placebo)		0.138
95% CI for Hedges' g		-0.7391, 1.0160

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 15		
n	10	10
LS Mean (SE)	-7.99 (1.519)	-7.89 (1.522)
95% CI for the LS Mean	-11.21, -4.76	-11.12, -4.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.10 (2.193)
95% CI for the LS Mean		-4.55, 4.74
p-value		0.9658
Hedges' g (Zuranolone vs. Placebo)		0.019
95% CI for Hedges' g		-0.8579, 0.8952
Day 21		
n	10	10
LS Mean (SE)	-6.69 (1.747)	-9.19 (1.749)
95% CI for the LS Mean	-10.39, -2.98	-12.90, -5.48
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.50 (2.509)
95% CI for the LS Mean		-7.81, 2.80
p-value		0.3328
Hedges' g (Zuranolone vs. Placebo)		-0.427
95% CI for Hedges' g		-1.3139, 0.4590

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Day 45		
n	9	10
LS Mean (SE)	-10.81 (1.559)	-8.79 (1.504)
95% CI for the LS Mean	-14.16, -7.47	-12.04, -5.54
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.02 (2.217)
95% CI for the LS Mean		-2.73, 6.78
p-value		0.3766
Hedges' g (Zuranolone vs. Placebo)		0.401
95% CI for Hedges' g		-0.5088, 1.3102

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 3		
n	62	62
LS Mean (SE)	-2.49 (0.679)	-3.98 (0.676)
95% CI for the LS Mean	-3.83, -1.14	-5.32, -2.64
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.49 (0.959)
95% CI for the LS Mean		-3.39, 0.41
p-value		0.1226
Hedges' g (Zuranolone vs. Placebo)		-0.278
95% CI for Hedges' g		-0.6312, 0.0762
Day 8		
n	64	65
LS Mean (SE)	-6.12 (0.741)	-7.75 (0.733)
95% CI for the LS Mean	-7.59, -4.65	-9.21, -6.30
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.63 (1.042)
95% CI for the LS Mean		-3.70, 0.43
p-value		0.1193
Hedges' g (Zuranolone vs. Placebo)		-0.275
95% CI for Hedges' g		-0.6213, 0.0722

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 15		
n	63	64
LS Mean (SE)	-8.17 (0.860)	-10.01 (0.850)
95% CI for the LS Mean	-9.87, -6.47	-11.70, -8.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.84 (1.209)
95% CI for the LS Mean		-4.23, 0.55
p-value		0.1305
Hedges' g (Zuranolone vs. Placebo)		-0.269
95% CI for Hedges' g		-0.6179, 0.0809
Day 21		
n	63	64
LS Mean (SE)	-8.36 (0.773)	-10.01 (0.765)
95% CI for the LS Mean	-9.89, -6.83	-11.53, -8.50
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.65 (1.088)
95% CI for the LS Mean		-3.81, 0.50
p-value		0.1313
Hedges' g (Zuranolone vs. Placebo)		-0.268
95% CI for Hedges' g		-0.6174, 0.0814

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Day 45		
n	60	63
LS Mean (SE)	-8.87 (0.812)	-12.22 (0.797)
95% CI for the LS Mean	-10.48, -7.27	-13.80, -10.64
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.34 (1.138)
95% CI for the LS Mean		-5.60, -1.09
p-value		0.0039
Hedges' g (Zuranolone vs. Placebo)		-0.527
95% CI for Hedges' g		-0.8863, -0.1670

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.4.1.2 .2 .8 PPD in der Anamnese

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 3		
n	58	62
LS Mean (SE)	-2.81 (0.703)	-3.70 (0.676)
95% CI for the LS Mean	-4.21, -1.42	-5.03, -2.36
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.88 (0.976)
95% CI for the LS Mean		-2.81, 1.05
p-value		0.3685
Hedges' g (Zuranolone vs. Placebo)		-0.164
95% CI for Hedges' g		-0.5225, 0.1948
Day 8		
n	59	65
LS Mean (SE)	-6.34 (0.781)	-7.62 (0.742)
95% CI for the LS Mean	-7.89, -4.79	-9.09, -6.15
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.28 (1.078)
95% CI for the LS Mean		-3.41, 0.85
p-value		0.2371
Hedges' g (Zuranolone vs. Placebo)		-0.212
95% CI for Hedges' g		-0.5658, 0.1411

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 15		
n	59	64
LS Mean (SE)	-8.27 (0.871)	-10.10 (0.830)
95% CI for the LS Mean	-10.00, -6.55	-11.75, -8.46
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.83 (1.204)
95% CI for the LS Mean		-4.22, 0.55
p-value		0.1304
Hedges' g (Zuranolone vs. Placebo)		-0.273
95% CI for Hedges' g		-0.6286, 0.0822
Day 21		
n	58	65
LS Mean (SE)	-8.26 (0.808)	-9.99 (0.765)
95% CI for the LS Mean	-9.85, -6.66	-11.50, -8.48
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.73 (1.112)
95% CI for the LS Mean		-3.94, 0.47
p-value		0.1215
Hedges' g (Zuranolone vs. Placebo)		-0.280
95% CI for Hedges' g		-0.6356, 0.0759

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by History of PPD: 217-PPD-201B - ITT population

Page: 3 of 6

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Day 45		
n	55	64
LS Mean (SE)	-9.03 (0.842)	-11.98 (0.788)
95% CI for the LS Mean	-10.69, -7.36	-13.54, -10.42
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.95 (1.154)
95% CI for the LS Mean		-5.23, -0.67
p-value		0.0118
Hedges' g (Zuranolone vs. Placebo)		-0.467
95% CI for Hedges' g		-0.8325, -0.1020

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 3		
n	14	10
LS Mean (SE)	-0.96 (1.144)	-6.06 (1.364)
95% CI for the LS Mean	-3.33, 1.41	-8.89, -3.24
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-5.10 (1.812)
95% CI for the LS Mean		-8.85, -1.35
p-value		0.0099
Hedges' g (Zuranolone vs. Placebo)		-1.126
95% CI for Hedges' g		-1.9974, -0.2539
Day 8		
n	15	10
LS Mean (SE)	-4.65 (1.233)	-6.86 (1.510)
95% CI for the LS Mean	-7.20, -2.10	-9.99, -3.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.21 (1.987)
95% CI for the LS Mean		-6.32, 1.89
p-value		0.2764
Hedges' g (Zuranolone vs. Placebo)		-0.440
95% CI for Hedges' g		-1.2493, 0.3695

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 15		
n	14	10
LS Mean (SE)	-7.22 (1.702)	-8.06 (2.057)
95% CI for the LS Mean	-10.74, -3.70	-12.33, -3.80
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.84 (2.698)
95% CI for the LS Mean		-6.43, 4.74
p-value		0.7576
Hedges' g (Zuranolone vs. Placebo)		-0.125
95% CI for Hedges' g		-0.9372, 0.6874
Day 21		
n	15	9
LS Mean (SE)	-7.11 (1.399)	-10.33 (1.763)
95% CI for the LS Mean	-10.03, -4.20	-13.99, -6.68
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.22 (2.287)
95% CI for the LS Mean		-7.96, 1.52
p-value		0.1734
Hedges' g (Zuranolone vs. Placebo)		-0.573
95% CI for Hedges' g		-1.4147, 0.2695

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Day 45		
n	14	9
LS Mean (SE)	-8.88 (1.514)	-11.06 (1.871)
95% CI for the LS Mean	-12.02, -5.74	-14.94, -7.18
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.18 (2.443)
95% CI for the LS Mean		-7.23, 2.88
p-value		0.3822
Hedges' g (Zuranolone vs. Placebo)		-0.367
95% CI for Hedges' g		-1.2110, 0.4771

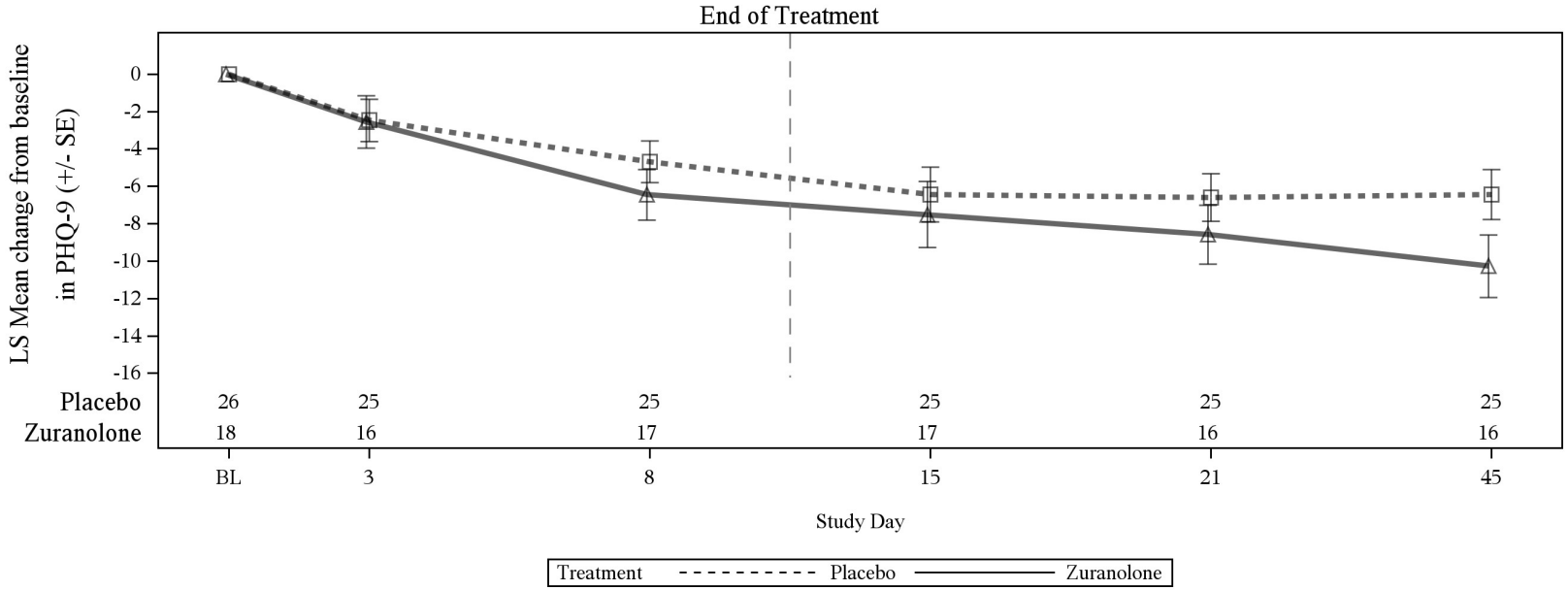
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-201-by.sas:t-phq9-mmrm-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.4.1.2 .3 Darstellung über die Zeit

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 18-24



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

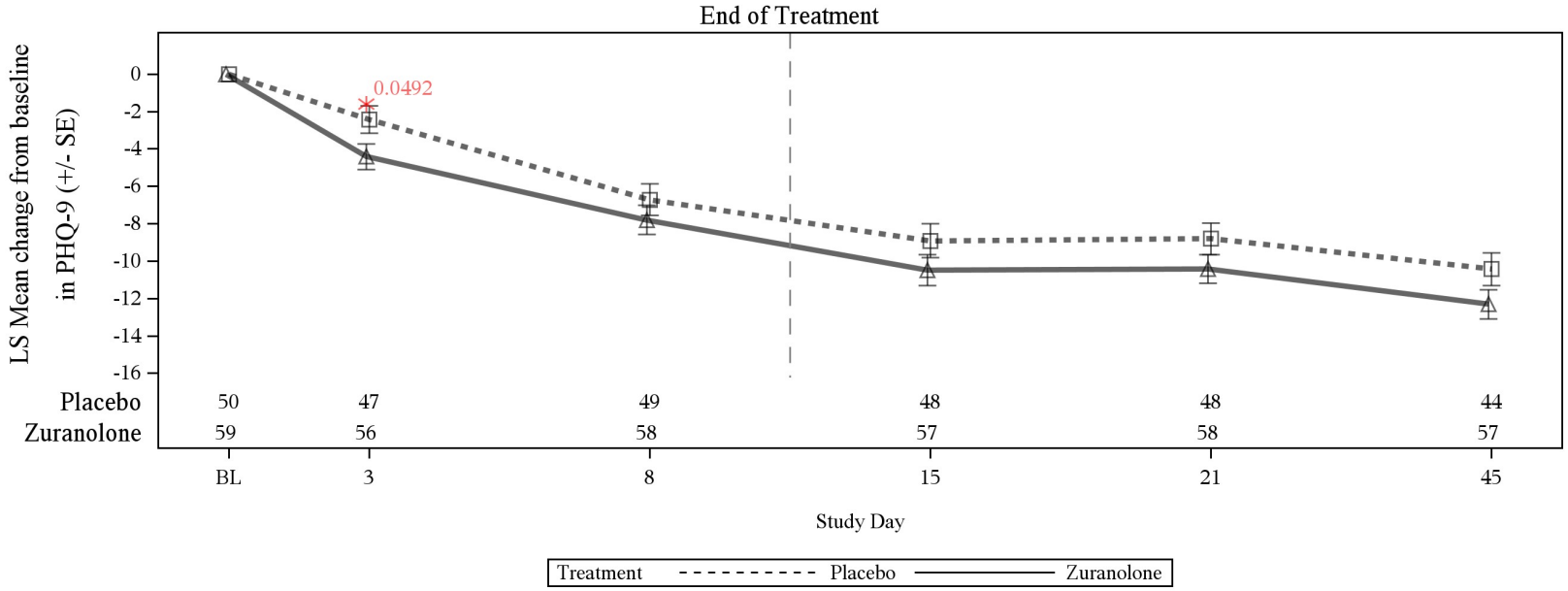
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 25-45



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

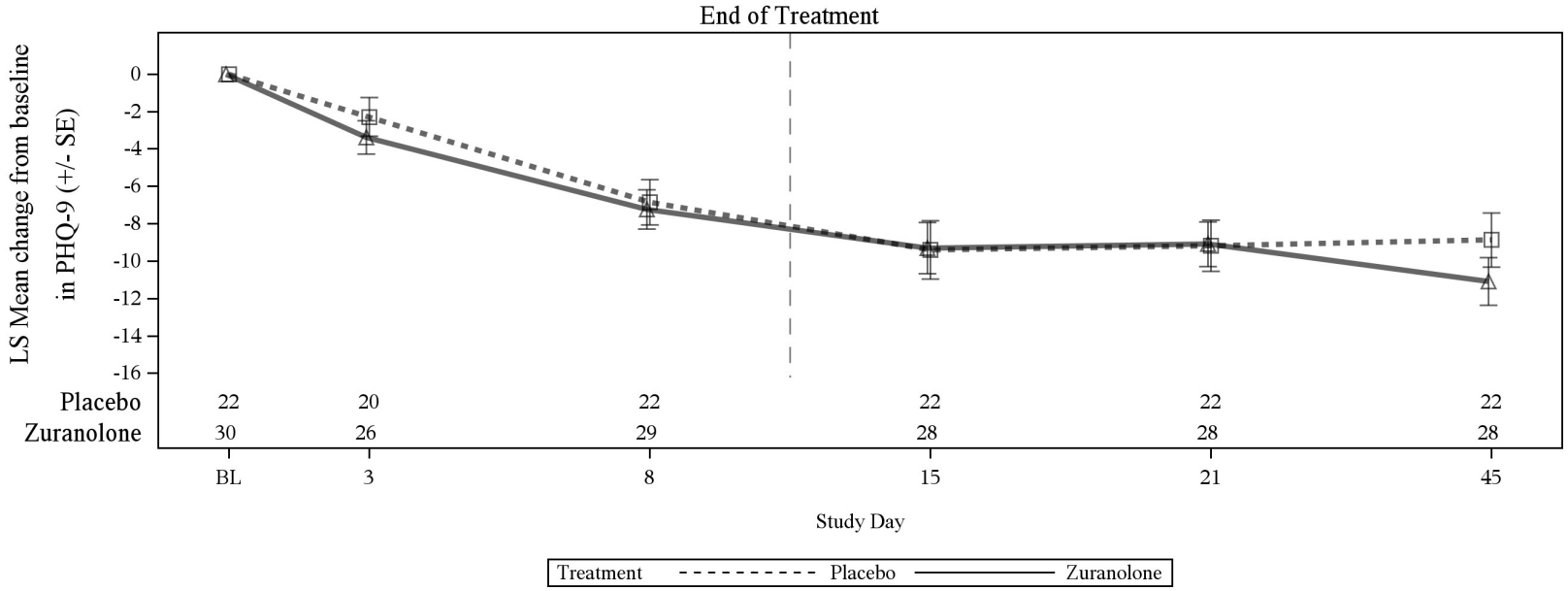
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

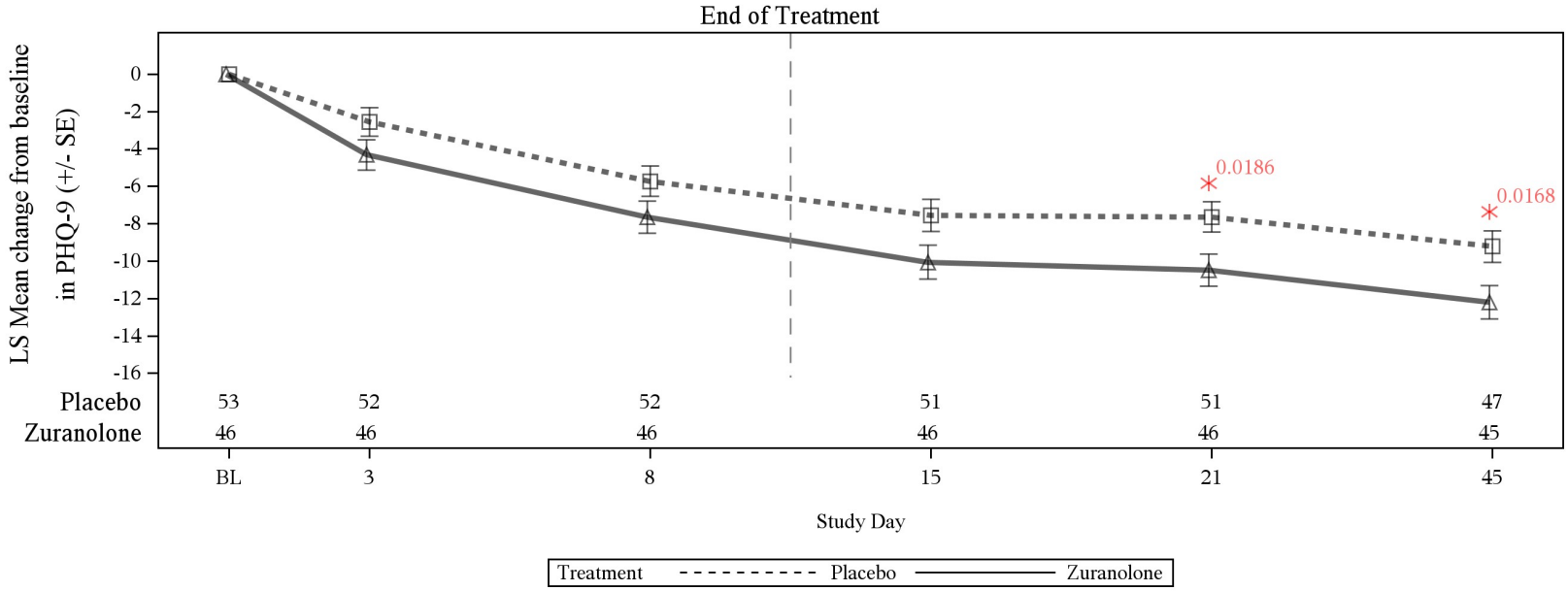
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

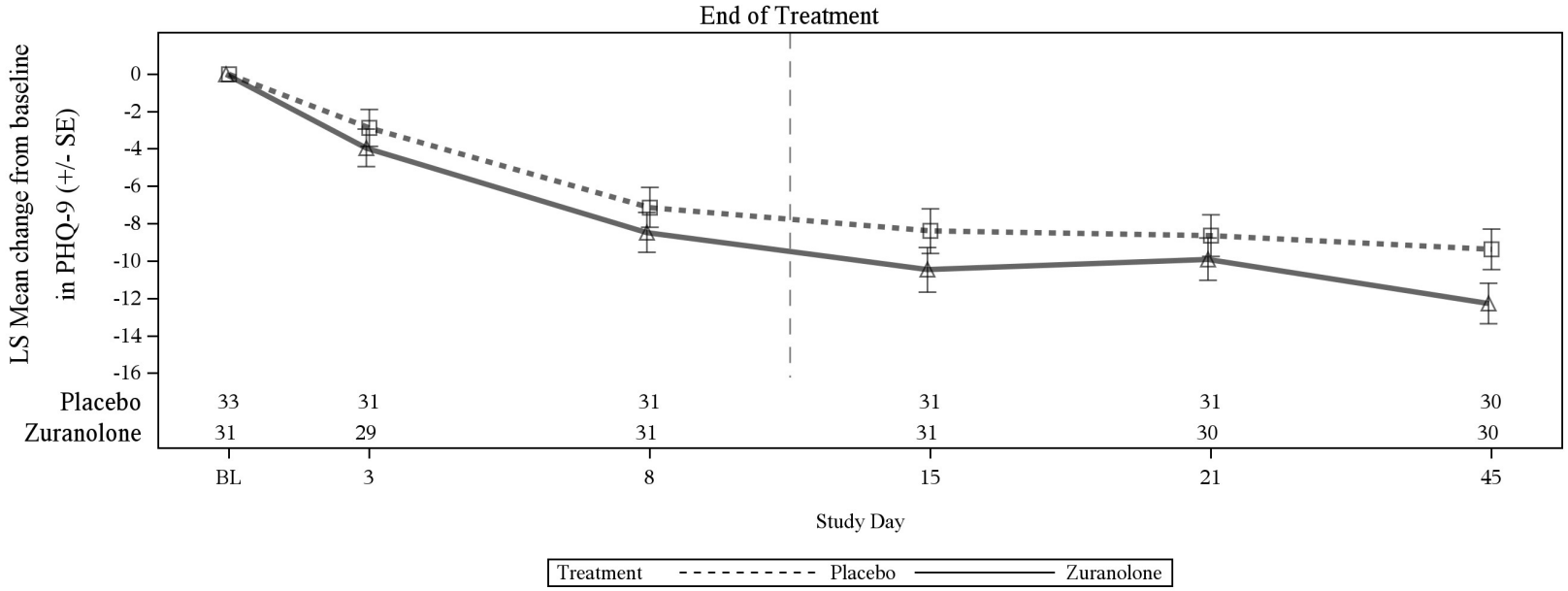
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

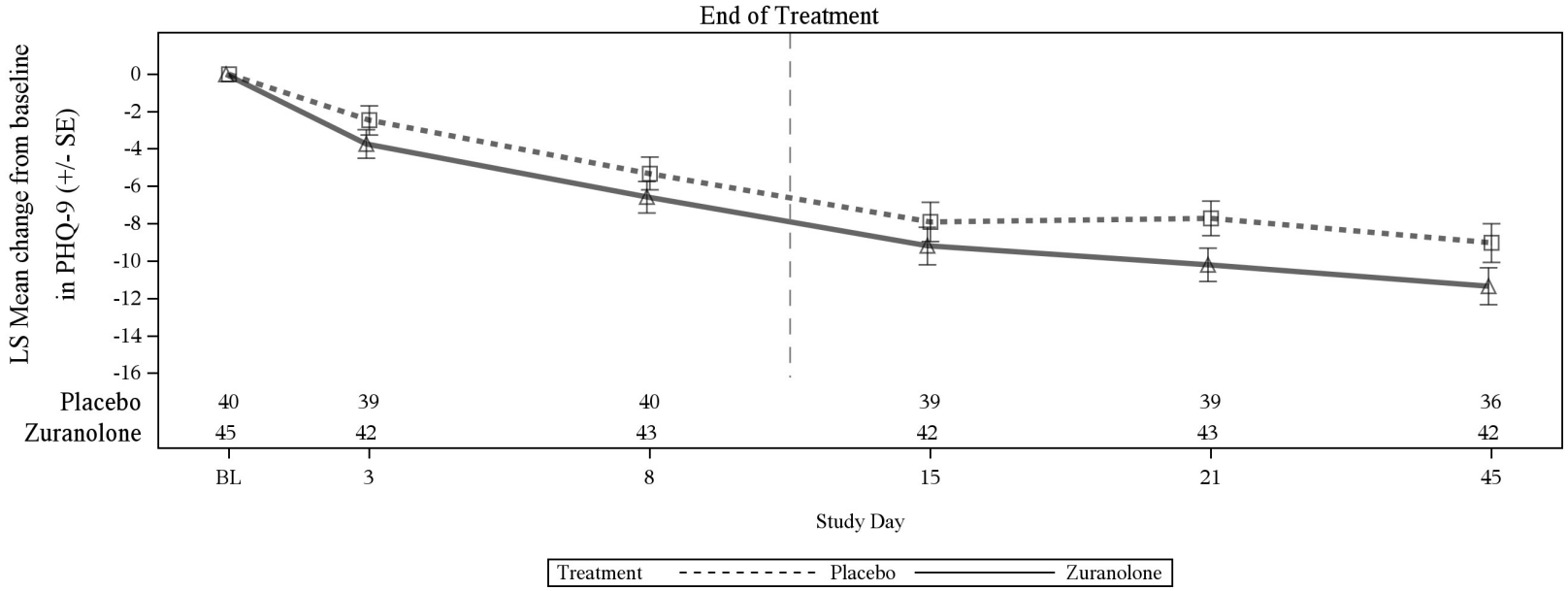
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

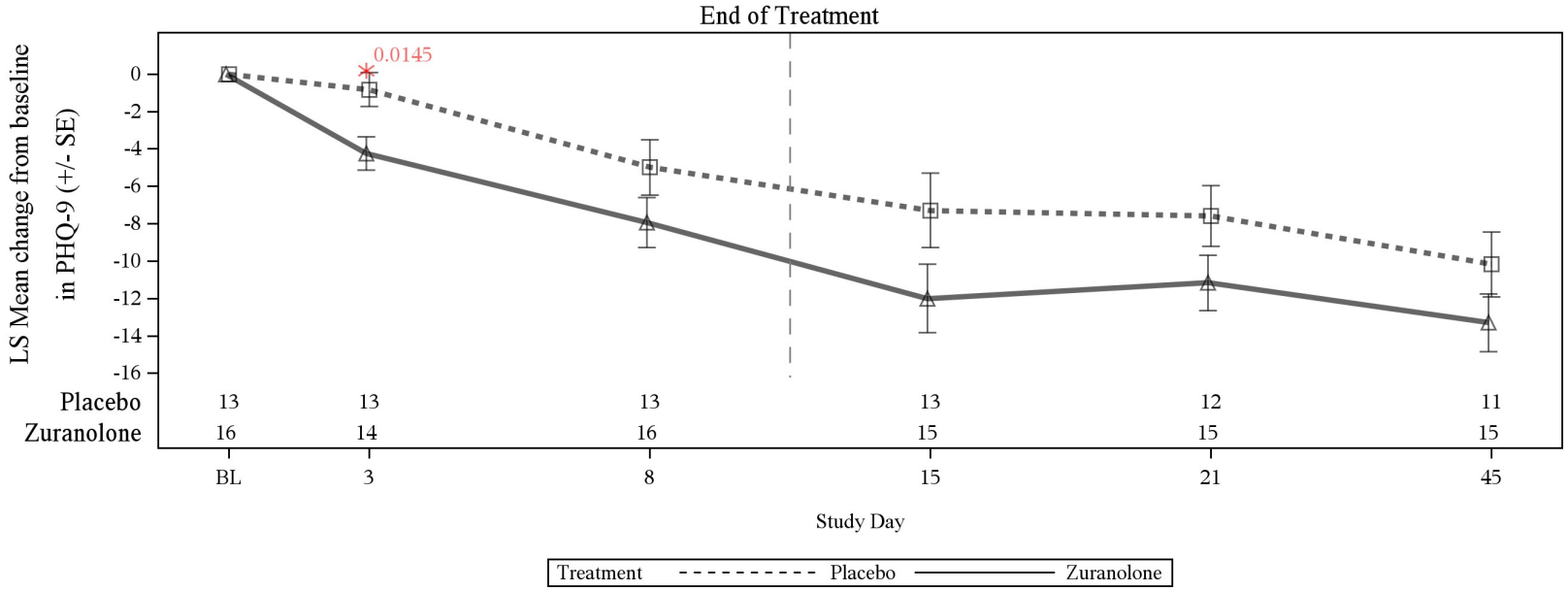
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

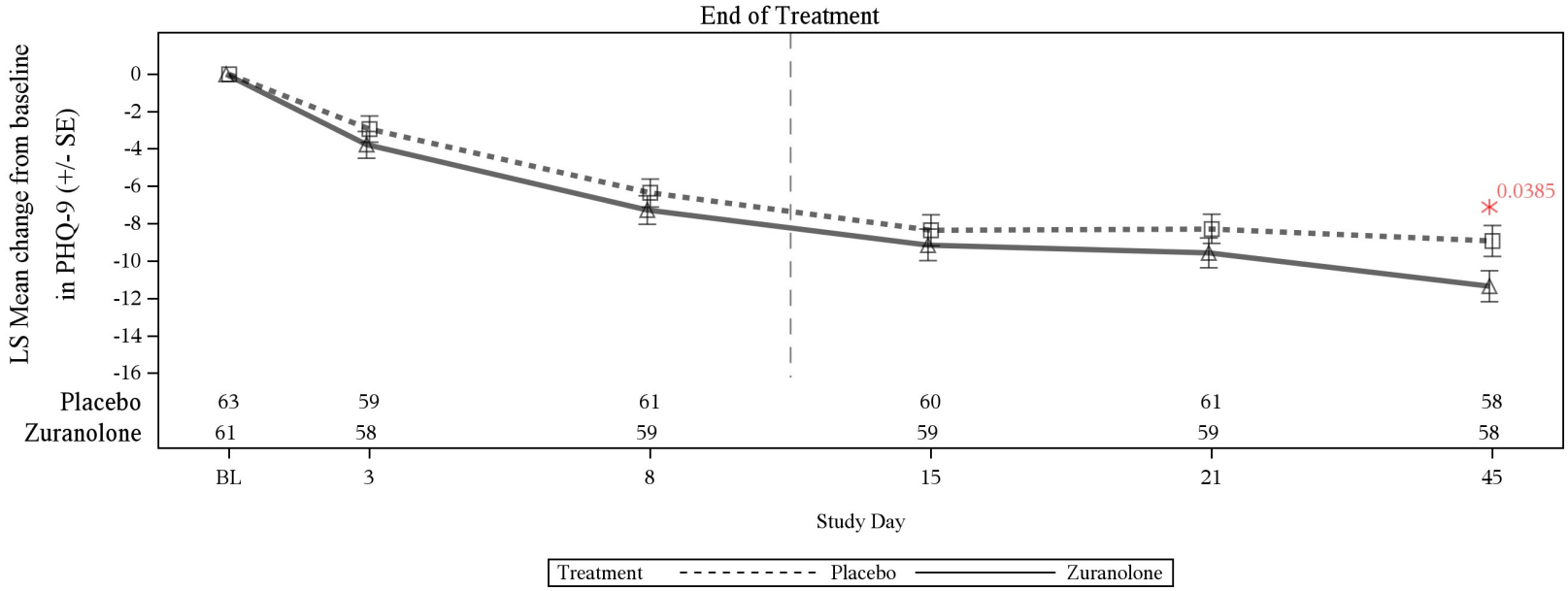
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

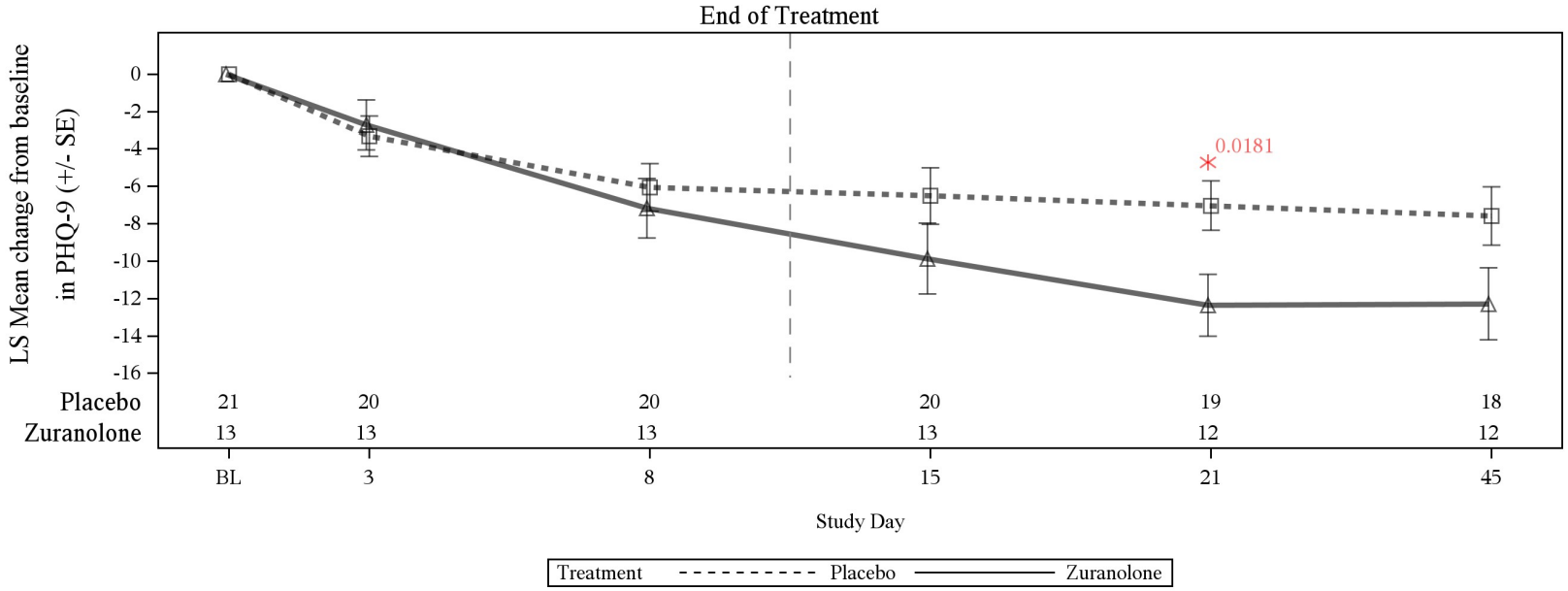
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

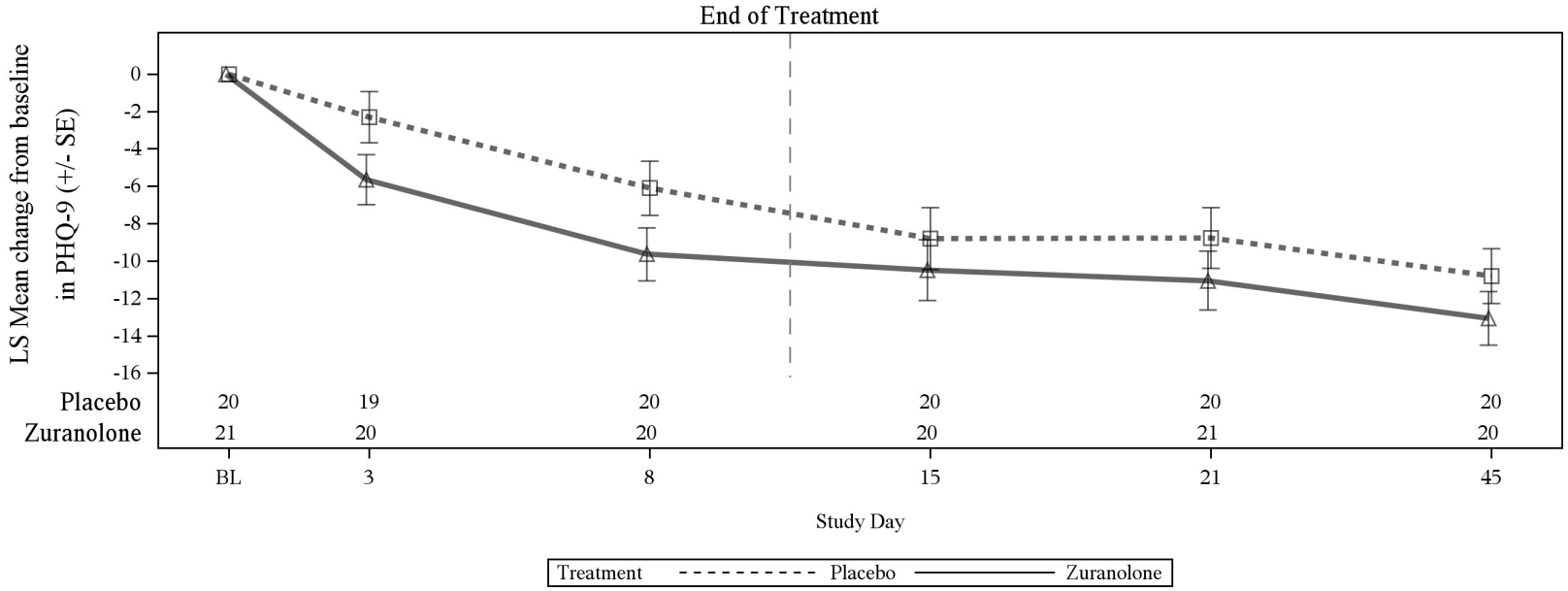
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

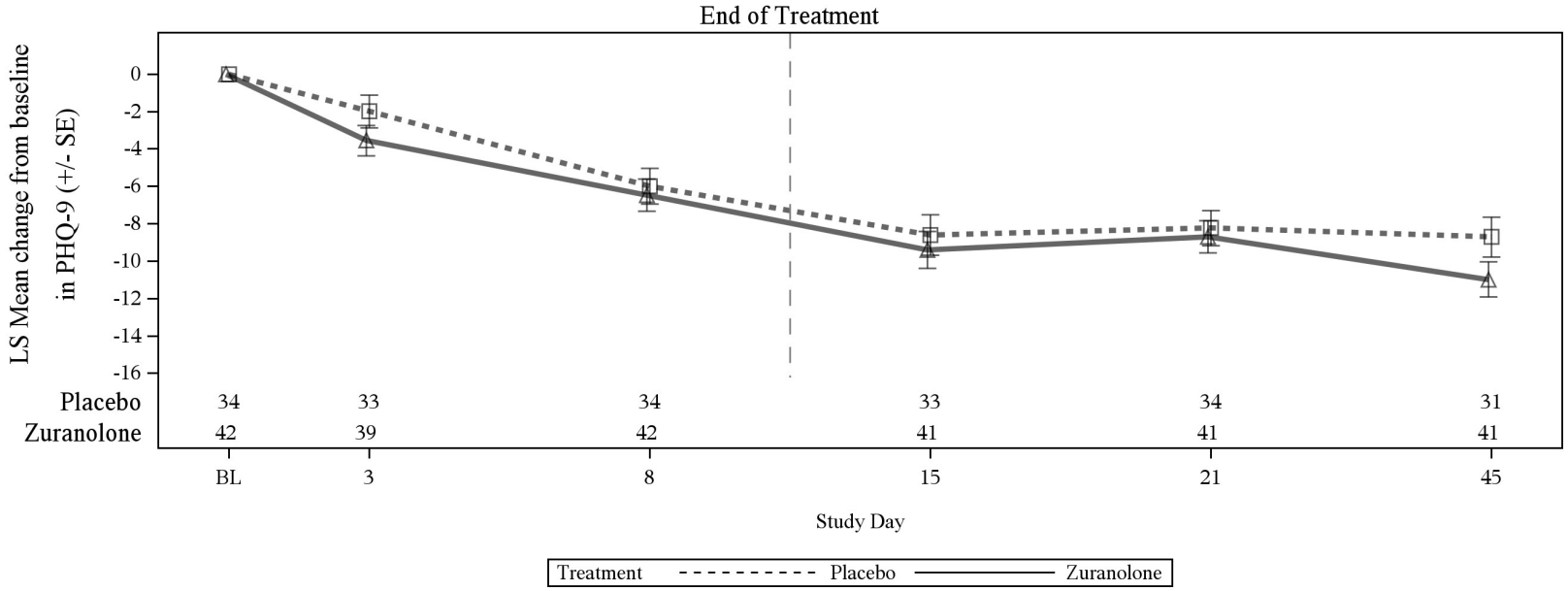
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

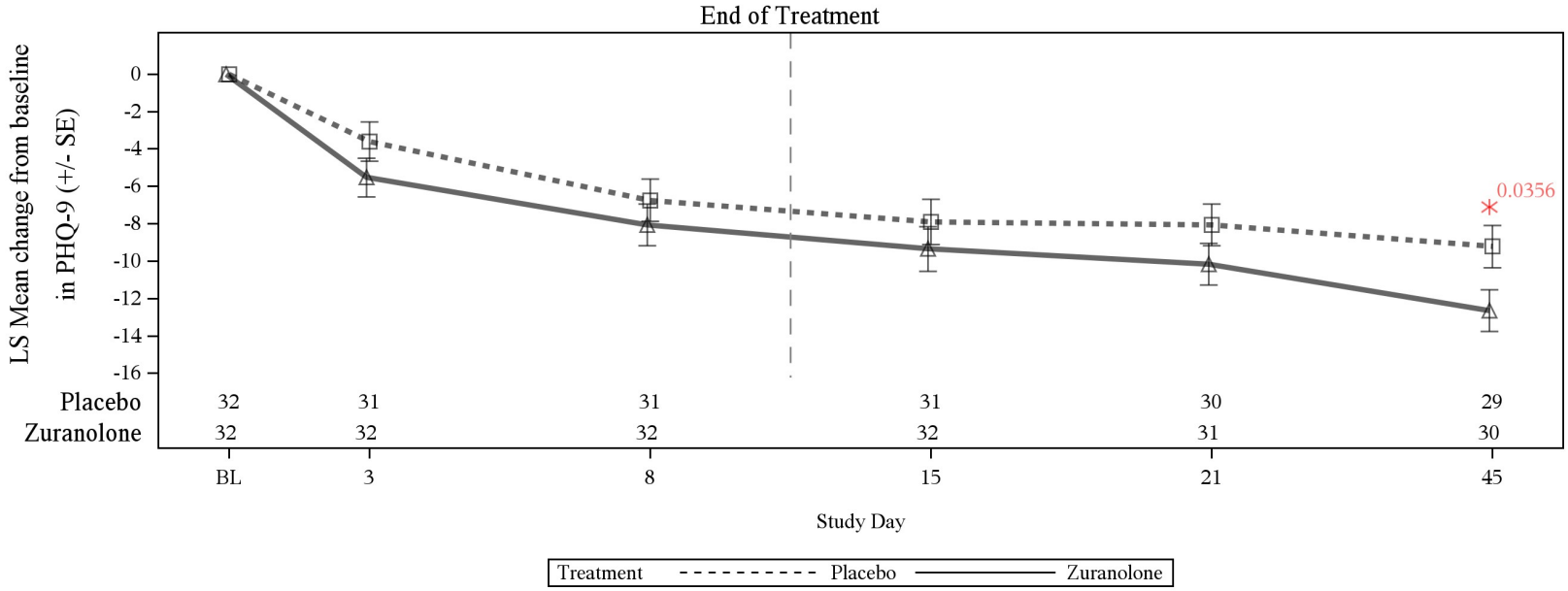
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = $p < 0.05$.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

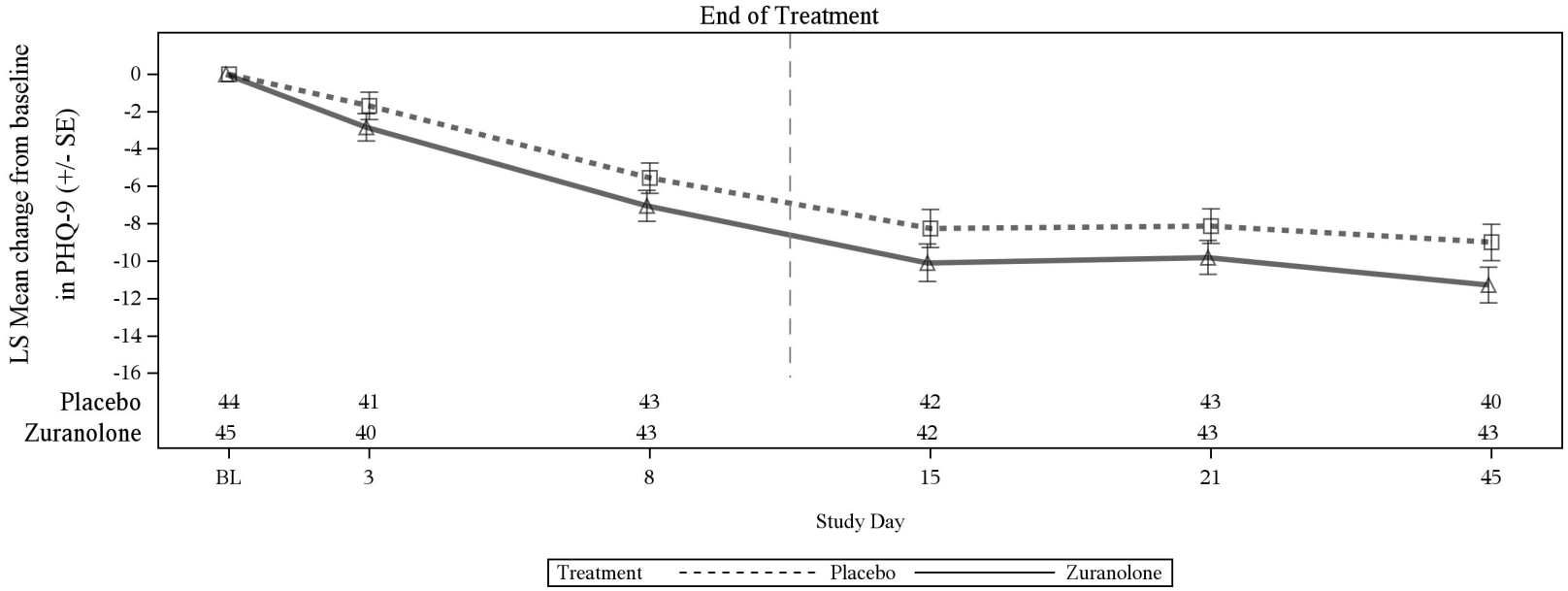
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

Page: 13 of 17

Onset of PPD = Postpartum



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

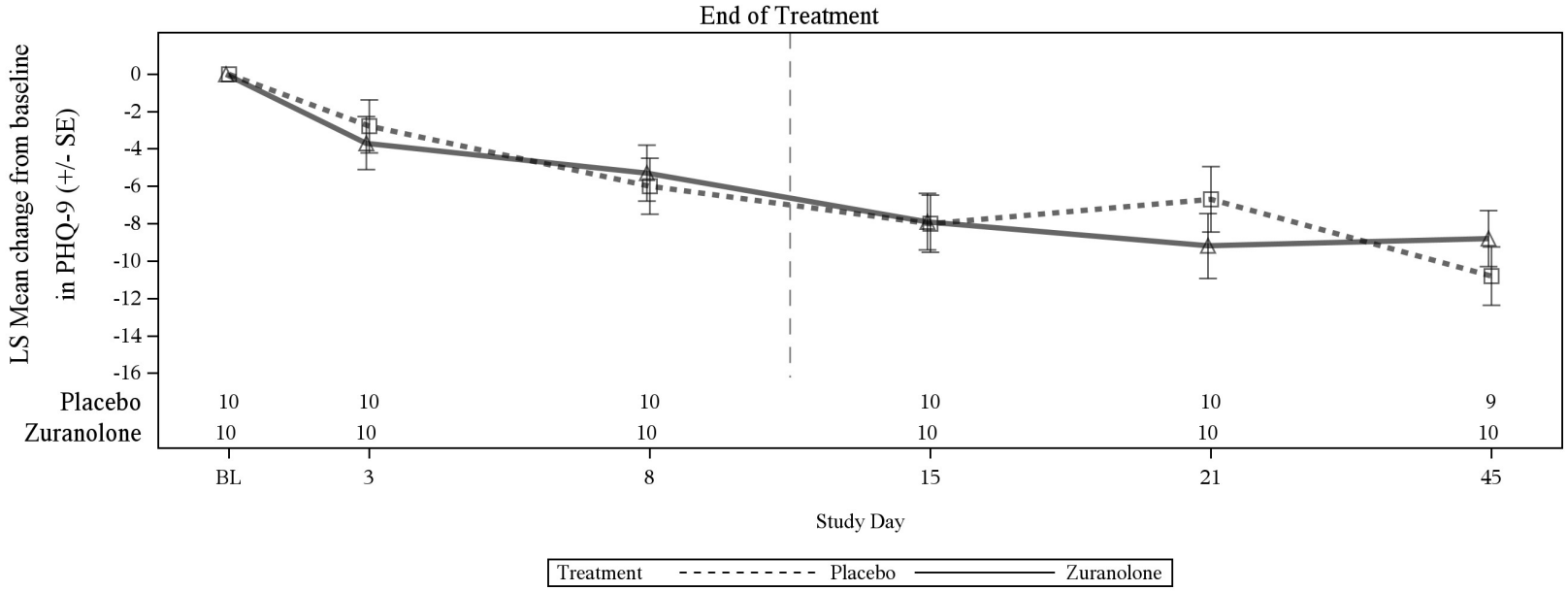
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

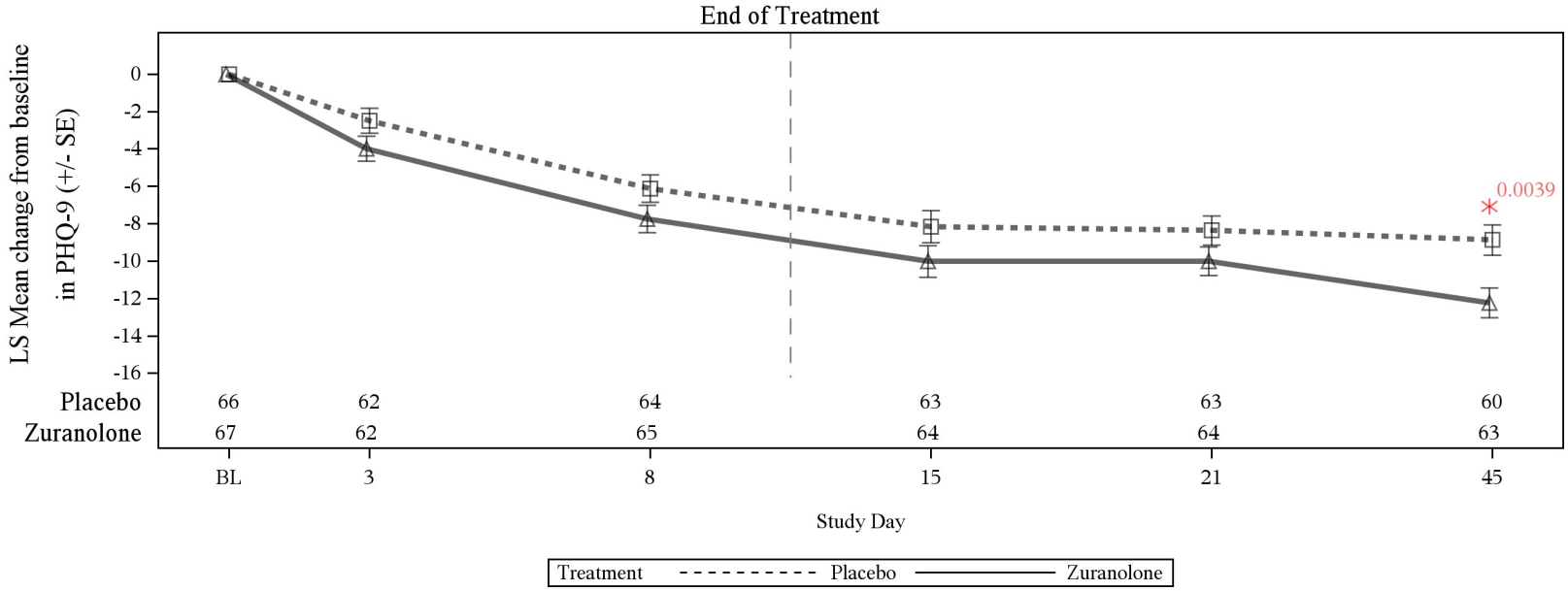
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

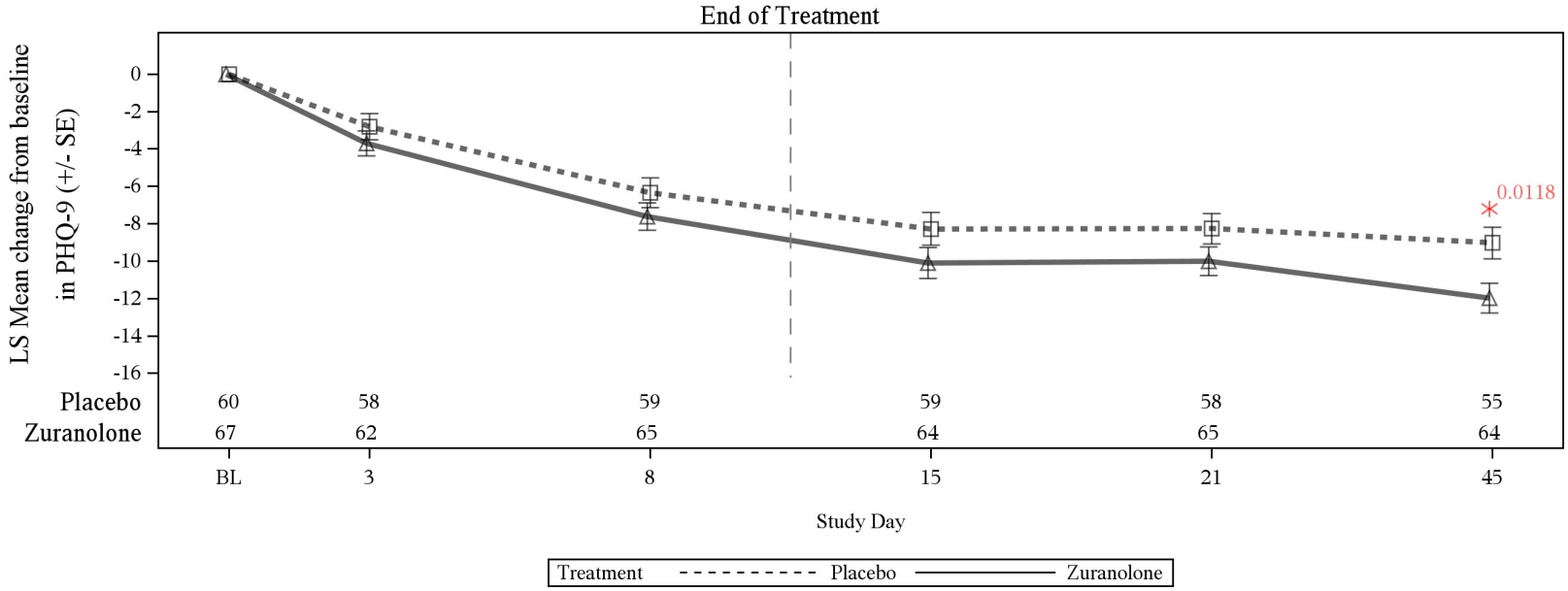
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

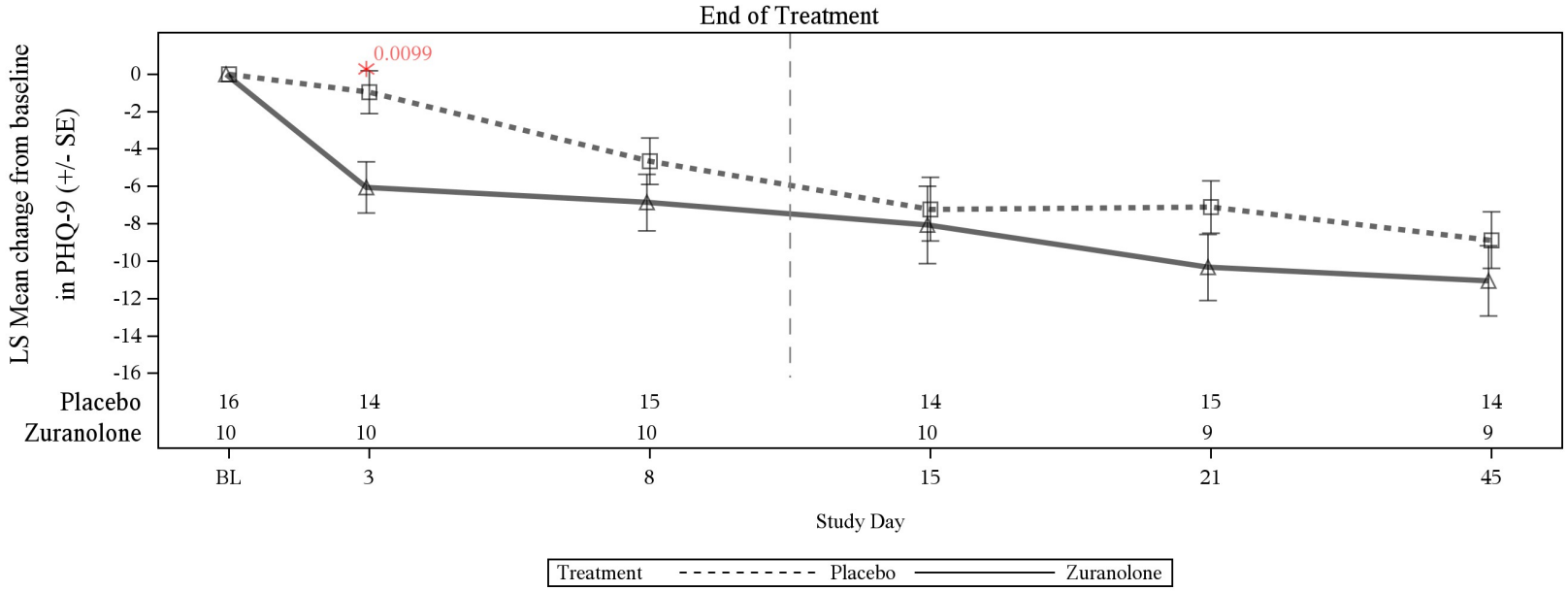
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: LS = Least-squares; SE = Standard error; BL = Baseline; * = p < 0.05.

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-201-by.sas:f-phq9-mmrm-201-by-itta.rtf **Run Date:** 29JUL2025

4.4.2 Ansprechen

4.4.2.1 Responder-Analysen

4.4.2.1 .1 ITT-Population

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with a response, n (%) [2]	19 (25.3)	24 (31.6)
Number of subjects with missing evaluation, n (%)	3 (4.0)	4 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.242
95% CI for the RR		(0.754, 2.043)
p-value for RR		0.3948
OR - Odds Ratio (Zuranolone vs. Placebo)		1.381
95% CI for the OR		(0.678, 2.813)
p-value for OR		0.3739
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.
[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-ovr.sas:t-phq9-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with a response, n (%) [2]	36 (48.0)	51 (67.1)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.392
95% CI for the RR		(1.057, 1.834)
p-value for RR		0.0184
OR - Odds Ratio (Zuranolone vs. Placebo)		2.476
95% CI for the OR		(1.245, 4.925)
p-value for OR		0.0098
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-ovr.sas:t-phq9-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with a response, n (%) [2]	45 (60.0)	56 (73.7)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.223
95% CI for the RR		(0.976, 1.533)
p-value for RR		0.0801
OR - Odds Ratio (Zuranolone vs. Placebo)		2.068
95% CI for the OR		(0.988, 4.329)
p-value for OR		0.0539
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-ovr.sas:t-phq9-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with a response, n (%) [2]	51 (68.0)	56 (73.7)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.079
95% CI for the RR		(0.883, 1.318)
p-value for RR		0.4553
OR - Odds Ratio (Zuranolone vs. Placebo)		1.423
95% CI for the OR		(0.680, 2.977)
p-value for OR		0.3487
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-ovr.sas:t-phq9-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	49 (65.3)	63 (82.9)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.264
95% CI for the RR		(1.044, 1.530)
p-value for RR		0.0166
OR - Odds Ratio (Zuranolone vs. Placebo)		2.875
95% CI for the OR		(1.259, 6.563)
p-value for OR		0.0122
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-ovr.sas:t-phq9-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.4.2.1 .2 Subgruppen

4.4.2.1 .2 .1 Interaktionstest

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	45 (60.0)	56 (73.7)	
Number of subjects with response at Day 45, n (%)	49 (65.3)	63 (82.9)	
Age Group (years)			0.4540
Day 15			
18 - 24, n / N (%)	14/25 (56.0)	10/17 (58.8)	
25 - 45, n / N (%)	31/50 (62.0)	46/59 (78.0)	
Day 45			
18 - 24, n / N (%)	16/25 (64.0)	13/17 (76.5)	
25 - 45, n / N (%)	33/50 (66.0)	50/59 (84.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-int.sas:t-phq9-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.4042
Day 15			
<28, n / N (%)	17/22 (77.3)	20/30 (66.7)	
>=28, n / N (%)	28/53 (52.8)	36/46 (78.3)	
Day 45			
<28, n / N (%)	18/22 (81.8)	24/30 (80.0)	
>=28, n / N (%)	31/53 (58.5)	39/46 (84.8)	
Race Group (Black or African American, White)			0.8696
Day 15			
Black or African American, n / N (%)	21/32 (65.6)	24/31 (77.4)	
White, n / N (%)	22/40 (55.0)	31/44 (70.5)	
Day 45			
Black or African American, n / N (%)	22/32 (68.8)	27/31 (87.1)	
White, n / N (%)	25/40 (62.5)	35/44 (79.5)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-int.sas:t-phq9-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.0757
Day 15			
Yes, n / N (%)	5/13 (38.5)	12/16 (75.0)	
No, n / N (%)	40/62 (64.5)	44/60 (73.3)	
Day 45			
Yes, n / N (%)	9/13 (69.2)	14/16 (87.5)	
No, n / N (%)	40/62 (64.5)	49/60 (81.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-int.sas:t-phq9-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.3638(a) 0.6295(b) 0.5599(c)
Day 15			
<=24.9, n / N (%)	9/21 (42.9)	9/13 (69.2)	
25-29.9, n / N (%)	13/20 (65.0)	14/21 (66.7)	
>=30, n / N (%)	23/34 (67.6)	33/42 (78.6)	
Day 45			
<=24.9, n / N (%)	12/21 (57.1)	11/13 (84.6)	
25-29.9, n / N (%)	17/20 (85.0)	17/21 (81.0)	
>=30, n / N (%)	20/34 (58.8)	35/42 (83.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-int.sas:t-phq9-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.9015
Day 15			
3rd Trimester, n / N (%)	18/32 (56.3)	23/32 (71.9)	
Postpartum, n / N (%)	27/43 (62.8)	33/44 (75.0)	
Day 45			
3rd Trimester, n / N (%)	21/32 (65.6)	28/32 (87.5)	
Postpartum, n / N (%)	28/43 (65.1)	35/44 (79.5)	
Family History of PPD			0.5355
Day 15			
Yes, n / N (%)	7/10 (70.0)	7/10 (70.0)	
No/Unknown, n / N (%)	38/65 (58.5)	49/66 (74.2)	
Day 45			
Yes, n / N (%)	8/10 (80.0)	9/10 (90.0)	
No/Unknown, n / N (%)	41/65 (63.1)	54/66 (81.8)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-int.sas:t-phq9-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.3124
Day 15			
1st Episode, n / N (%)	37/59 (62.7)	50/66 (75.8)	
Recurrent Episode, n / N (%)	8/16 (50.0)	6/10 (60.0)	
Day 45			
1st Episode, n / N (%)	41/59 (69.5)	54/66 (81.8)	
Recurrent Episode, n / N (%)	8/16 (50.0)	9/10 (90.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	4/8 (50.0)	8/10 (80.0)	
>=20, n / N (%)	41/67 (61.2)	48/66 (72.7)	
Day 45			
<20, n / N (%)	5/8 (62.5)	9/10 (90.0)	
>=20, n / N (%)	44/67 (65.7)	54/66 (81.8)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-int.sas:t-phq9-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

4.4.2.1 .2 .2 Subgruppenanalysen

4.4.2.1 .2 .2 .1 Alter

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 1 of 6

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 3		
Number of subjects with a response, n (%) [2]	5 (20.0)	6 (35.3)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.694
95% CI for the RR		(0.641, 4.476)
p-value for RR		0.2876
Day 8		
Number of subjects with a response, n (%) [2]	8 (32.0)	12 (70.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.118
95% CI for the RR		(1.107, 4.051)
p-value for RR		0.0234

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 2 of 6

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 15		
Number of subjects with a response, n (%) [2]	14 (56.0)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.008
95% CI for the RR		(0.575, 1.768)
p-value for RR		0.9768
Day 21		
Number of subjects with a response, n (%) [2]	14 (56.0)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.109
95% CI for the RR		(0.697, 1.766)
p-value for RR		0.6621

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 3 of 6

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 45		
Number of subjects with a response, n (%) [2]	16 (64.0)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.147
95% CI for the RR		(0.757, 1.739)
p-value for RR		0.5182

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 3		
Number of subjects with a response, n (%) [2]	14 (28.0)	18 (30.5)
Number of subjects with missing evaluation, n (%)	3 (6.0)	3 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.100
95% CI for the RR		(0.616, 1.966)
p-value for RR		0.7474
Day 8		
Number of subjects with a response, n (%) [2]	28 (56.0)	39 (66.1)
Number of subjects with missing evaluation, n (%)	1 (2.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.192
95% CI for the RR		(0.882, 1.611)
p-value for RR		0.2538

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 15		
Number of subjects with a response, n (%) [2]	31 (62.0)	46 (78.0)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.270
95% CI for the RR		(0.987, 1.632)
p-value for RR		0.0627
Day 21		
Number of subjects with a response, n (%) [2]	37 (74.0)	45 (76.3)
Number of subjects with missing evaluation, n (%)	2 (4.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.041
95% CI for the RR		(0.838, 1.292)
p-value for RR		0.7189

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 6 of 6

Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 45		
Number of subjects with a response, n (%) [2]	33 (66.0)	50 (84.7)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.296
95% CI for the RR		(1.035, 1.623)
p-value for RR		0.0238

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.4.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 3		
Number of subjects with a response, n (%) [2]	4 (18.2)	9 (30.0)
Number of subjects with missing evaluation, n (%)	2 (9.1)	4 (13.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.637
95% CI for the RR		(0.590, 4.537)
p-value for RR		0.3437
Day 8		
Number of subjects with a response, n (%) [2]	10 (45.5)	20 (66.7)
Number of subjects with missing evaluation, n (%)	0	1 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.455
95% CI for the RR		(0.894, 2.368)
p-value for RR		0.1315

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 2 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 15		
Number of subjects with a response, n (%) [2]	17 (77.3)	20 (66.7)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.856
95% CI for the RR		(0.615, 1.191)
p-value for RR		0.3551
Day 21		
Number of subjects with a response, n (%) [2]	16 (72.7)	19 (63.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.864
95% CI for the RR		(0.603, 1.237)
p-value for RR		0.4245

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 3 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 45		
Number of subjects with a response, n (%) [2]	18 (81.8)	24 (80.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.970
95% CI for the RR		(0.736, 1.278)
p-value for RR		0.8276

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 4 of 6

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 3		
Number of subjects with a response, n (%) [2]	15 (28.3)	15 (32.6)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.151
95% CI for the RR		(0.644, 2.058)
p-value for RR		0.6358
Day 8		
Number of subjects with a response, n (%) [2]	26 (49.1)	31 (67.4)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.372
95% CI for the RR		(0.982, 1.918)
p-value for RR		0.0640

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 15		
Number of subjects with a response, n (%) [2]	28 (52.8)	36 (78.3)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.480
95% CI for the RR		(1.103, 1.984)
p-value for RR		0.0089
Day 21		
Number of subjects with a response, n (%) [2]	35 (66.0)	37 (80.4)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.217
95% CI for the RR		(0.959, 1.543)
p-value for RR		0.1056

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 45		
Number of subjects with a response, n (%) [2]	31 (58.5)	39 (84.8)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.448
95% CI for the RR		(1.125, 1.863)
p-value for RR		0.0040

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.4.2.1 .2 .2 .3 Abstammung

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 3		
Number of subjects with a response, n (%) [2]	10 (31.3)	10 (32.3)
Number of subjects with missing evaluation, n (%)	1 (3.1)	2 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.037
95% CI for the RR		(0.515, 2.092)
p-value for RR		0.9182
Day 8		
Number of subjects with a response, n (%) [2]	16 (50.0)	23 (74.2)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.491
95% CI for the RR		(1.015, 2.191)
p-value for RR		0.0418

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 15		
Number of subjects with a response, n (%) [2]	21 (65.6)	24 (77.4)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.186
95% CI for the RR		(0.870, 1.615)
p-value for RR		0.2806
Day 21		
Number of subjects with a response, n (%) [2]	22 (68.8)	24 (77.4)
Number of subjects with missing evaluation, n (%)	1 (3.1)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.132
95% CI for the RR		(0.846, 1.514)
p-value for RR		0.4051

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 45		
Number of subjects with a response, n (%) [2]	22 (68.8)	27 (87.1)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.273
95% CI for the RR		(0.972, 1.667)
p-value for RR		0.0792

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 3		
Number of subjects with a response, n (%) [2]	9 (22.5)	13 (29.5)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.301
95% CI for the RR		(0.632, 2.678)
p-value for RR		0.4754
Day 8		
Number of subjects with a response, n (%) [2]	19 (47.5)	27 (61.4)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.280
95% CI for the RR		(0.865, 1.893)
p-value for RR		0.2168

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	22 (55.0)	31 (70.5)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.269
95% CI for the RR		(0.911, 1.767)
p-value for RR		0.1584
Day 21		
Number of subjects with a response, n (%) [2]	26 (65.0)	32 (72.7)
Number of subjects with missing evaluation, n (%)	1 (2.5)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.108
95% CI for the RR		(0.841, 1.461)
p-value for RR		0.4655

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	25 (62.5)	35 (79.5)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.261
95% CI for the RR		(0.953, 1.668)
p-value for RR		0.1045

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.4.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 3		
Number of subjects with a response, n (%) [2]	1 (7.7)	4 (25.0)
Number of subjects with missing evaluation, n (%)	0	2 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		3.362
95% CI for the RR		(0.408, 27.725)
p-value for RR		0.2599
Day 8		
Number of subjects with a response, n (%) [2]	5 (38.5)	12 (75.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.017
95% CI for the RR		(0.950, 4.285)
p-value for RR		0.0678

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 15		
Number of subjects with a response, n (%) [2]	5 (38.5)	12 (75.0)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.017
95% CI for the RR		(0.963, 4.227)
p-value for RR		0.0629
Day 21		
Number of subjects with a response, n (%) [2]	8 (61.5)	12 (75.0)
Number of subjects with missing evaluation, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.261
95% CI for the RR		(0.755, 2.107)
p-value for RR		0.3762

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 45		
Number of subjects with a response, n (%) [2]	9 (69.2)	14 (87.5)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.308
95% CI for the RR		(0.870, 1.966)
p-value for RR		0.1975

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 3		
Number of subjects with a response, n (%) [2]	18 (29.0)	20 (33.3)
Number of subjects with missing evaluation, n (%)	3 (4.8)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.126
95% CI for the RR		(0.675, 1.879)
p-value for RR		0.6496
Day 8		
Number of subjects with a response, n (%) [2]	31 (50.0)	39 (65.0)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.275
95% CI for the RR		(0.947, 1.716)
p-value for RR		0.1092

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 15		
Number of subjects with a response, n (%) [2]	40 (64.5)	44 (73.3)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.115
95% CI for the RR		(0.879, 1.413)
p-value for RR		0.3691
Day 21		
Number of subjects with a response, n (%) [2]	43 (69.4)	44 (73.3)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.037
95% CI for the RR		(0.834, 1.289)
p-value for RR		0.7436

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 45		
Number of subjects with a response, n (%) [2]	40 (64.5)	49 (81.7)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.241
95% CI for the RR		(1.001, 1.540)
p-value for RR		0.0493

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.4.2.1 .2 .2 .5 BMI

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 3		
Number of subjects with a response, n (%) [2]	6 (28.6)	5 (38.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.293
95% CI for the RR		(0.512, 3.263)
p-value for RR		0.5869
Day 8		
Number of subjects with a response, n (%) [2]	10 (47.6)	9 (69.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.396
95% CI for the RR		(0.792, 2.461)
p-value for RR		0.2488

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 15		
Number of subjects with a response, n (%) [2]	9 (42.9)	9 (69.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.551
95% CI for the RR		(0.878, 2.742)
p-value for RR		0.1308
Day 21		
Number of subjects with a response, n (%) [2]	13 (61.9)	11 (84.6)
Number of subjects with missing evaluation, n (%)	2 (9.5)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.313
95% CI for the RR		(0.873, 1.973)
p-value for RR		0.1910

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 45		
Number of subjects with a response, n (%) [2]	12 (57.1)	11 (84.6)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.422
95% CI for the RR		(0.926, 2.183)
p-value for RR		0.1077

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 3		
Number of subjects with a response, n (%) [2]	6 (30.0)	8 (38.1)
Number of subjects with missing evaluation, n (%)	1 (5.0)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.298
95% CI for the RR		(0.550, 3.061)
p-value for RR		0.5512
Day 8		
Number of subjects with a response, n (%) [2]	11 (55.0)	14 (66.7)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.239
95% CI for the RR		(0.752, 2.042)
p-value for RR		0.4005

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	13 (65.0)	14 (66.7)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.048
95% CI for the RR		(0.670, 1.640)
p-value for RR		0.8359
Day 21		
Number of subjects with a response, n (%) [2]	15 (75.0)	14 (66.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.909
95% CI for the RR		(0.612, 1.349)
p-value for RR		0.6343

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 45		
Number of subjects with a response, n (%) [2]	17 (85.0)	17 (81.0)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.974
95% CI for the RR		(0.735, 1.290)
p-value for RR		0.8516

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 3		
Number of subjects with a response, n (%) [2]	7 (20.6)	11 (26.2)
Number of subjects with missing evaluation, n (%)	1 (2.9)	3 (7.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.252
95% CI for the RR		(0.551, 2.845)
p-value for RR		0.5920
Day 8		
Number of subjects with a response, n (%) [2]	15 (44.1)	28 (66.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.487
95% CI for the RR		(0.976, 2.264)
p-value for RR		0.0645

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 15		
Number of subjects with a response, n (%) [2]	23 (67.6)	33 (78.6)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.143
95% CI for the RR		(0.857, 1.525)
p-value for RR		0.3641
Day 21		
Number of subjects with a response, n (%) [2]	23 (67.6)	31 (73.8)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.074
95% CI for the RR		(0.819, 1.408)
p-value for RR		0.6073

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 45		
Number of subjects with a response, n (%) [2]	20 (58.8)	35 (83.3)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.394
95% CI for the RR		(1.022, 1.902)
p-value for RR		0.0362

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.4.2.1 .2 .2 .6 Beginn der PPD

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 6

Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 3		
Number of subjects with a response, n (%) [2]	12 (37.5)	13 (40.6)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.091
95% CI for the RR		(0.599, 1.984)
p-value for RR		0.7765
Day 8		
Number of subjects with a response, n (%) [2]	16 (50.0)	23 (71.9)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.447
95% CI for the RR		(0.973, 2.153)
p-value for RR		0.0684

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 15		
Number of subjects with a response, n (%) [2]	18 (56.3)	23 (71.9)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.286
95% CI for the RR		(0.887, 1.866)
p-value for RR		0.1845
Day 21		
Number of subjects with a response, n (%) [2]	22 (68.8)	26 (81.3)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.190
95% CI for the RR		(0.898, 1.576)
p-value for RR		0.2265

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 45		
Number of subjects with a response, n (%) [2]	21 (65.6)	28 (87.5)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.342
95% CI for the RR		(1.016, 1.773)
p-value for RR		0.0381

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 3		
Number of subjects with a response, n (%) [2]	7 (16.3)	11 (25.0)
Number of subjects with missing evaluation, n (%)	2 (4.7)	4 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.513
95% CI for the RR		(0.655, 3.495)
p-value for RR		0.3322
Day 8		
Number of subjects with a response, n (%) [2]	20 (46.5)	28 (63.6)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.348
95% CI for the RR		(0.923, 1.969)
p-value for RR		0.1223

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	27 (62.8)	33 (75.0)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.177
95% CI for the RR		(0.888, 1.560)
p-value for RR		0.2578
Day 21		
Number of subjects with a response, n (%) [2]	29 (67.4)	30 (68.2)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.996
95% CI for the RR		(0.750, 1.323)
p-value for RR		0.9782

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	28 (65.1)	35 (79.5)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.204
95% CI for the RR		(0.927, 1.563)
p-value for RR		0.1642

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.4.2.1 .2 .2 .7 PPD in der Familie

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 6

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 3		
Number of subjects with a response, n (%) [2]	3 (30.0)	2 (20.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.795
95% CI for the RR		(0.196, 3.221)
p-value for RR		0.7477
Day 8		
Number of subjects with a response, n (%) [2]	6 (60.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.192
95% CI for the RR		(0.668, 2.128)
p-value for RR		0.5521

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	7 (70.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.192
95% CI for the RR		(0.734, 1.936)
p-value for RR		0.4773
Day 21		
Number of subjects with a response, n (%) [2]	6 (60.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.391
95% CI for the RR		(0.780, 2.480)
p-value for RR		0.2634

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	8 (80.0)	9 (90.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.341
95% CI for the RR		(0.888, 2.025)
p-value for RR		0.1628

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 3		
Number of subjects with a response, n (%) [2]	16 (24.6)	22 (33.3)
Number of subjects with missing evaluation, n (%)	3 (4.6)	4 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.333
95% CI for the RR		(0.779, 2.283)
p-value for RR		0.2944
Day 8		
Number of subjects with a response, n (%) [2]	30 (46.2)	45 (68.2)
Number of subjects with missing evaluation, n (%)	1 (1.5)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.455
95% CI for the RR		(1.072, 1.974)
p-value for RR		0.0161

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 5 of 6

Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	38 (58.5)	49 (74.2)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.250
95% CI for the RR		(0.977, 1.601)
p-value for RR		0.0764
Day 21		
Number of subjects with a response, n (%) [2]	45 (69.2)	49 (74.2)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.056
95% CI for the RR		(0.856, 1.303)
p-value for RR		0.6118

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	41 (63.1)	54 (81.8)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.277
95% CI for the RR		(1.031, 1.582)
p-value for RR		0.0249

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.4.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 3		
Number of subjects with a response, n (%) [2]	15 (25.4)	20 (30.3)
Number of subjects with missing evaluation, n (%)	1 (1.7)	4 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.179
95% CI for the RR		(0.674, 2.065)
p-value for RR		0.5636
Day 8		
Number of subjects with a response, n (%) [2]	29 (49.2)	45 (68.2)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.373
95% CI for the RR		(1.013, 1.860)
p-value for RR		0.0409

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 6

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	37 (62.7)	50 (75.8)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.195
95% CI for the RR		(0.942, 1.517)
p-value for RR		0.1420
Day 21		
Number of subjects with a response, n (%) [2]	41 (69.5)	49 (74.2)
Number of subjects with missing evaluation, n (%)	1 (1.7)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.057
95% CI for the RR		(0.852, 1.312)
p-value for RR		0.6145

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	41 (69.5)	54 (81.8)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.165
95% CI for the RR		(0.953, 1.425)
p-value for RR		0.1369

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 3		
Number of subjects with a response, n (%) [2]	4 (25.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.827
95% CI for the RR		(0.633, 5.272)
p-value for RR		0.2647
Day 8		
Number of subjects with a response, n (%) [2]	7 (43.8)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.566
95% CI for the RR		(0.835, 2.938)
p-value for RR		0.1620

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	8 (50.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.371
95% CI for the RR		(0.689, 2.725)
p-value for RR		0.3688
Day 21		
Number of subjects with a response, n (%) [2]	10 (62.5)	7 (70.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.279
95% CI for the RR		(0.711, 2.302)
p-value for RR		0.4114

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	8 (50.0)	9 (90.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.056
95% CI for the RR		(1.096, 3.855)
p-value for RR		0.0246

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response (4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

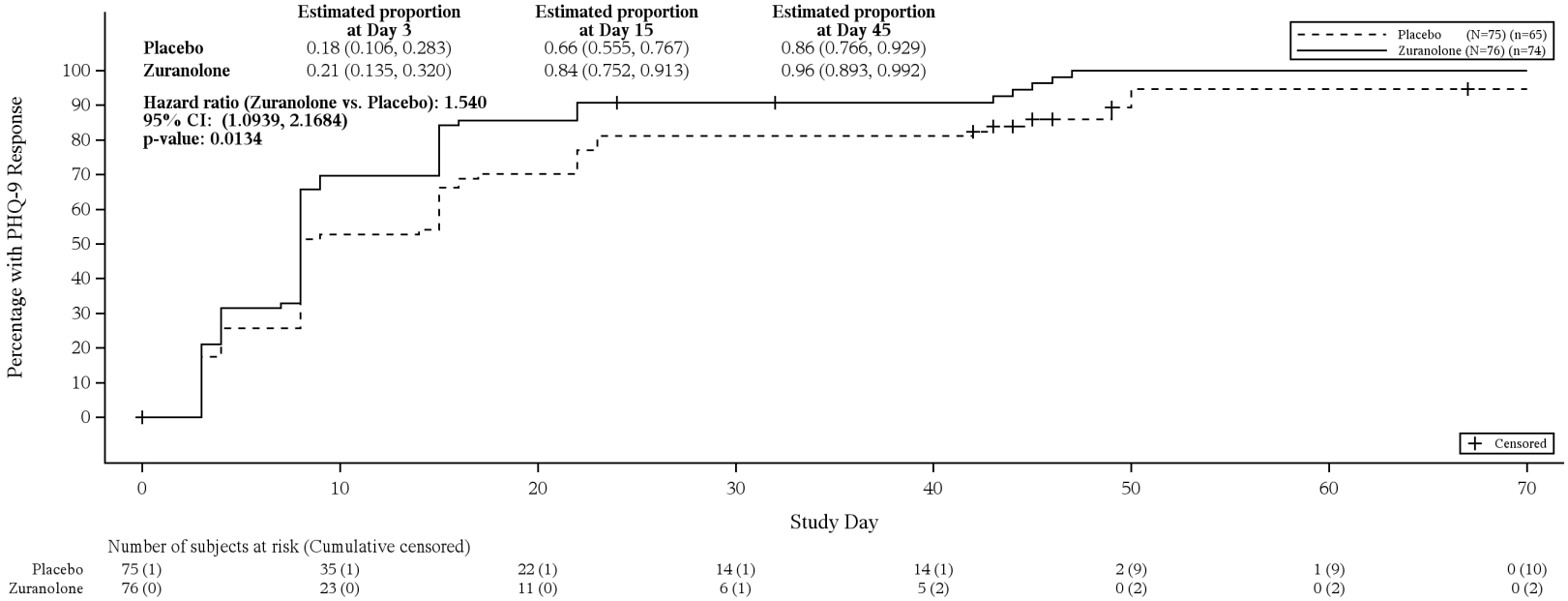
Source: biib125/v_a/germany_amnog/t-phq9-resp15-201-by.sas:t-phq9-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.4.2.2 TTE-Analysen

4.4.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-phq9-resp15-tte-201-ovr.sas:f-phq9-resp15-tte-201-ovr-itta.rtf **Run Date:** 16DEC2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	65 (86.7)	74 (97.4)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	22.0 (15.0 , 45.0)	15.0 (8.0 , 15.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.540
95% CI for the HR		(1.0939 , 2.1684)
p-value for the HR		0.0134

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-ovr.sas:t-phq9-resp15-tte-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.4.2.2 .2 Subgruppen

4.4.2.2 .2 .1 Interaktionstest

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	65 (86.7)	74 (97.4)	
Age Group (years)			
18 - 24, n / N (%)	20/25 (80.0)	17/17 (100.0)	0.2079
25 - 45, n / N (%)	45/50 (90.0)	57/59 (96.6)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	20/22 (90.9)	29/30 (96.7)	0.5046
>=28, n / N (%)	45/53 (84.9)	45/46 (97.8)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	29/32 (90.6)	31/31 (100.0)	0.7424
White, n / N (%)	33/40 (82.5)	42/44 (95.5)	
Antidepressant Use at Baseline			
Yes, n / N (%)	12/13 (92.3)	16/16 (100.0)	0.1448
No, n / N (%)	53/62 (85.5)	58/60 (96.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-int.sas:t-phq9-resp15-tte-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	16/21 (76.2)	13/13 (100.0)	0.4652(a)
25-29.9, n / N (%)	18/20 (90.0)	19/21 (90.5)	0.2253(b)
>=30, n / N (%)	31/34 (91.2)	42/42 (100.0)	0.6789(c)
Onset of PPD			
3rd Trimester, n / N (%)	27/32 (84.4)	31/32 (96.9)	0.8832
Postpartum, n / N (%)	38/43 (88.4)	43/44 (97.7)	
Family History of PPD			
Yes, n / N (%)	9/10 (90.0)	10/10 (100.0)	0.8917
No/Unknown, n / N (%)	56/65 (86.2)	64/66 (97.0)	
History of PPD			
1st Episode, n / N (%)	53/59 (89.8)	64/66 (97.0)	0.5304
Recurrent Episode, n / N (%)	12/16 (75.0)	10/10 (100.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	5/8 (62.5)	9/10 (90.0)	NA
>=20, n / N (%)	60/67 (89.6)	65/66 (98.5)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-int.sas:t-phq9-resp15-tte-201-int-itta.rtf **Run Date:** 29JUL2025

4.4.2.2 .2 .2 Subgruppenanalysen

4.4.2.2 .2 .2 .1 Alter

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	20 (80.0)	17 (100.0)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 15.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (9.0 , 23.0)	8.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	42.0 (16.0, NE)	15.0 (8.0 , 44.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.173
95% CI for the HR		(1.1014 , 4.2880)
p-value for the HR		0.0252

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	45 (90.0)	57 (96.6)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (NE, NE)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (8.0 , 43.0)	15.0 (8.0 , 16.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.262
95% CI for the HR		(0.8431 , 1.8889)
p-value for the HR		0.2582

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.4.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	20 (90.9)	29 (96.7)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 15.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	15.0 (15.0, NE)	15.0 (8.0 , 44.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.411
95% CI for the HR		(0.7816 , 2.5483)
p-value for the HR		0.2532

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	45 (84.9)	45 (97.8)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 16.0)	8.0 (7.0 , 8.0)
75th percentile - Q3 (95% CI)	22.5 (16.0 , 50.0)	15.0 (8.0 , 15.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.649
95% CI for the HR		(1.0736 , 2.5321)
p-value for the HR		0.0224

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.4.2.2 .2 .2 .3 Abstammung

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	29 (90.6)	31 (100.0)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (4.0 , 15.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	22.0 (8.0 , 45.0)	9.0 (8.0 , 15.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.386
95% CI for the HR		(0.8204 , 2.3409)
p-value for the HR		0.2226

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	33 (82.5)	42 (95.5)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	12.0 (8.0 , 16.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	23.0 (15.0, NE)	15.0 (8.0 , 44.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.627
95% CI for the HR		(1.0171 , 2.6022)
p-value for the HR		0.0423

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.4.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	12 (92.3)	16 (100.0)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 15.0)	5.5 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 42.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	42.0 (15.0, NE)	11.5 (8.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.517
95% CI for the HR		(1.0038 , 6.3092)
p-value for the HR		0.0491

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	53 (85.5)	58 (96.7)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	22.0 (15.0 , 43.0)	15.0 (8.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.334
95% CI for the HR		(0.9173 , 1.9405)
p-value for the HR		0.1315

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.4.2.2 .2 .2 .5 BMI

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	16 (76.2)	13 (100.0)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	3.0 (3.0 , 8.0)
50th percentile - median (95% CI)	12.0 (4.0 , 23.0)	8.0 (3.0 , 8.0)
75th percentile - Q3 (95% CI)	33.0 (15.0, NE)	8.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.047
95% CI for the HR		(0.9432 , 4.4408)
p-value for the HR		0.0700

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

Page: 2 of 3

BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	18 (90.0)	19 (90.5)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	3.5 (3.0 , 8.0)	4.0 (3.0 , 7.0)
50th percentile - median (95% CI)	8.0 (3.0 , 16.0)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	19.5 (8.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.306
95% CI for the HR		(0.6402 , 2.6659)
p-value for the HR		0.4627

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	31 (91.2)	42 (100.0)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	17.0 (15.0 , 42.0)	15.0 (8.0 , 15.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.317
95% CI for the HR		(0.8253 , 2.1013)
p-value for the HR		0.2483

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.4.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	27 (84.4)	31 (96.9)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 8.0)	3.5 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (4.0 , 15.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	23.0 (8.0, NE)	12.0 (8.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.454
95% CI for the HR		(0.8439 , 2.5064)
p-value for the HR		0.1774

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	38 (88.4)	43 (97.7)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	5.5 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 15.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	22.0 (15.0 , 50.0)	15.0 (8.0 , 43.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.612
95% CI for the HR		(1.0292 , 2.5246)
p-value for the HR		0.0370

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.4.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	9 (90.0)	10 (100.0)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 8.0)	7.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (3.0 , 15.0)	8.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	15.0 (8.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.975
95% CI for the HR		(0.6490 , 6.0106)
p-value for the HR		0.2307

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	56 (86.2)	64 (97.0)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	6.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	11.5 (8.0 , 15.0)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	22.0 (15.0 , 45.0)	15.0 (8.0 , 15.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.554
95% CI for the HR		(1.0719 , 2.2520)
p-value for the HR		0.0200

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.4.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	53 (89.8)	64 (97.0)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	22.0 (15.0 , 43.0)	15.0 (8.0 , 15.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.479
95% CI for the HR		(1.0152 , 2.1545)
p-value for the HR		0.0415

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	12 (75.0)	10 (100.0)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	3.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (3.0 , 22.0)	7.5 (3.0 , 22.0)
75th percentile - Q3 (95% CI)	45.0 (8.0, NE)	22.0 (7.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.698
95% CI for the HR		(0.9719 , 7.4914)
p-value for the HR		0.0567

NOTE 1: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

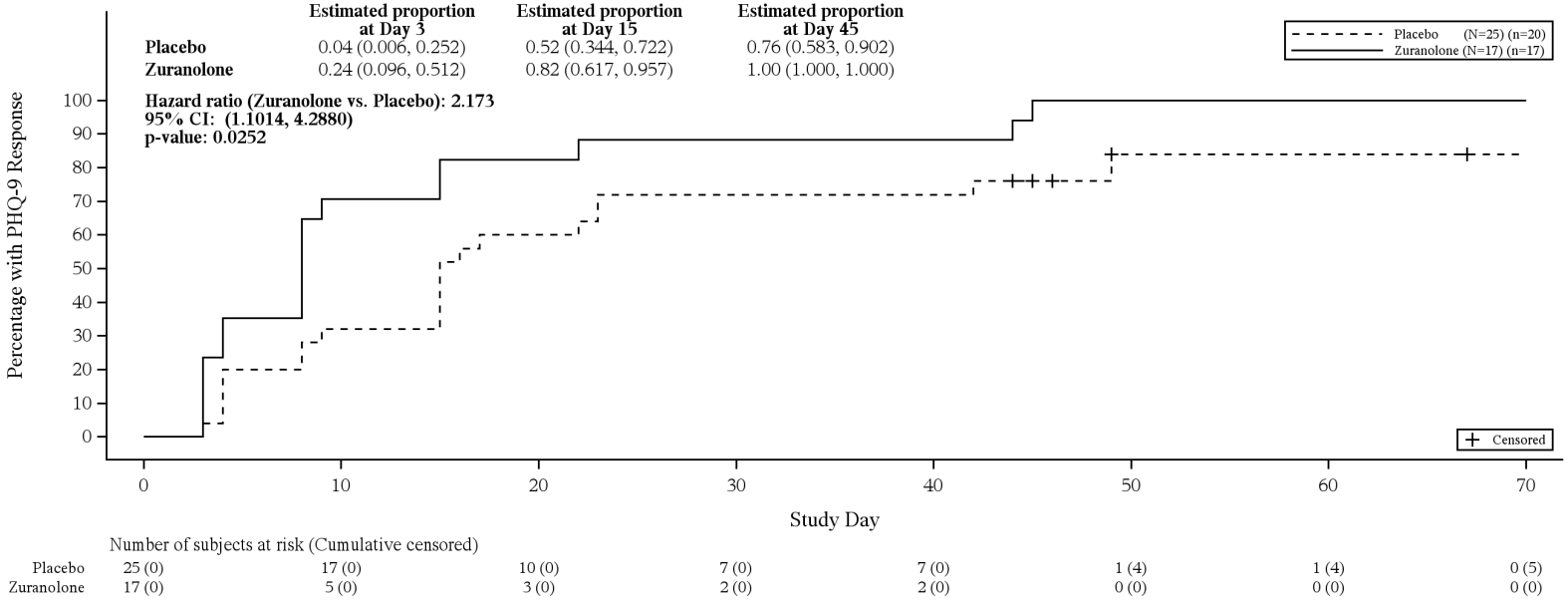
Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-201-by.sas:t-phq9-resp15-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.4.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 19

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

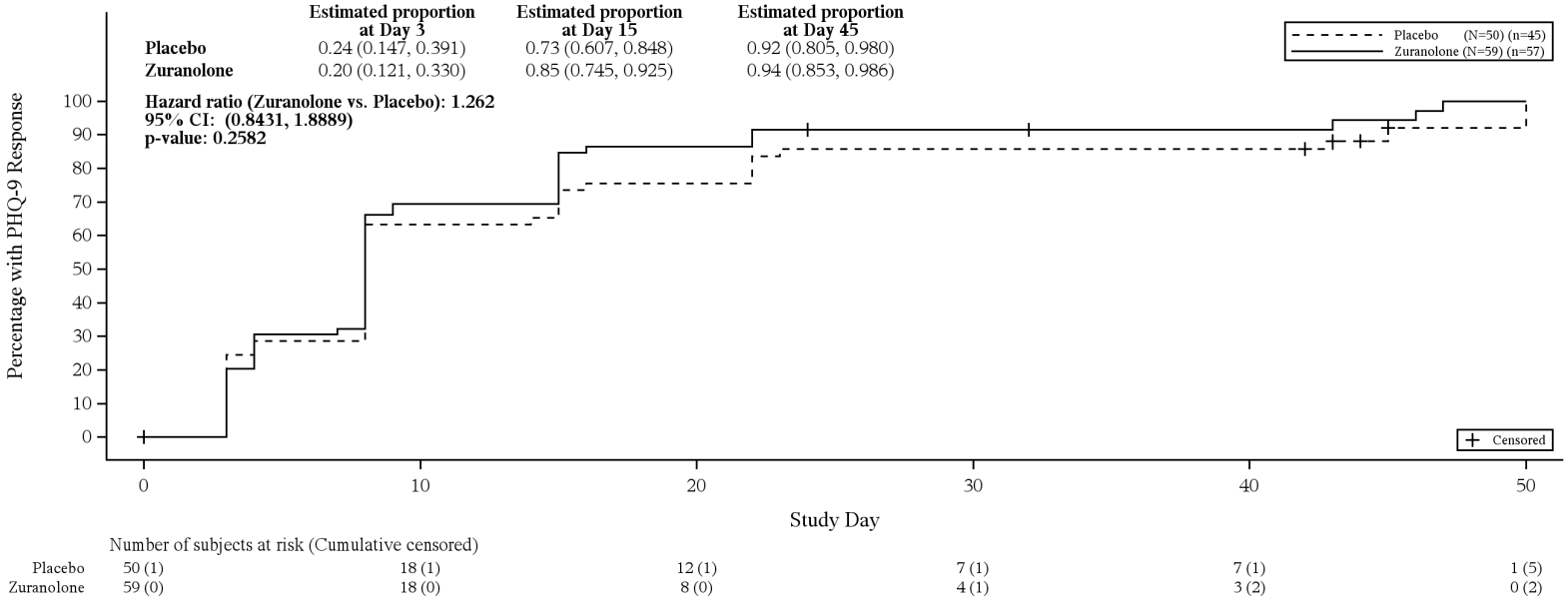
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-phq9-resp15-tte-201-by.sas:f-phq9-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

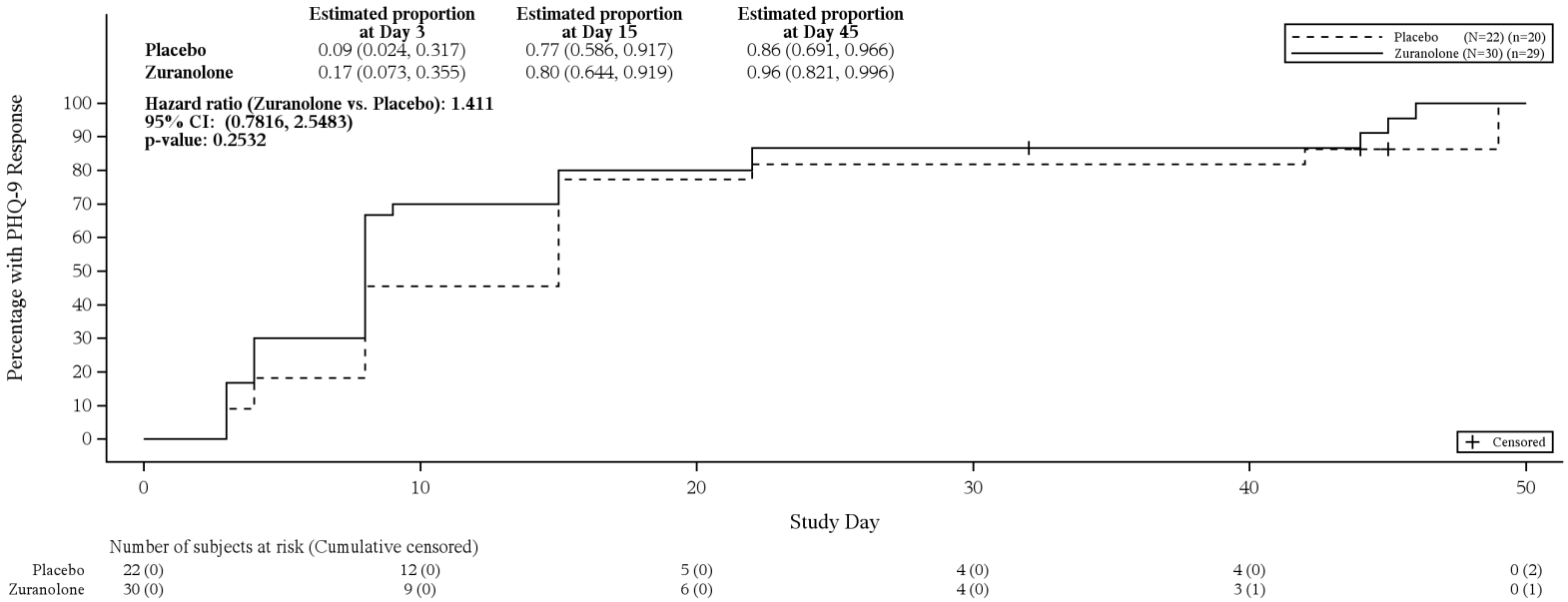
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-phq9-resp15-tte-201-by.sas:f-phq9-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

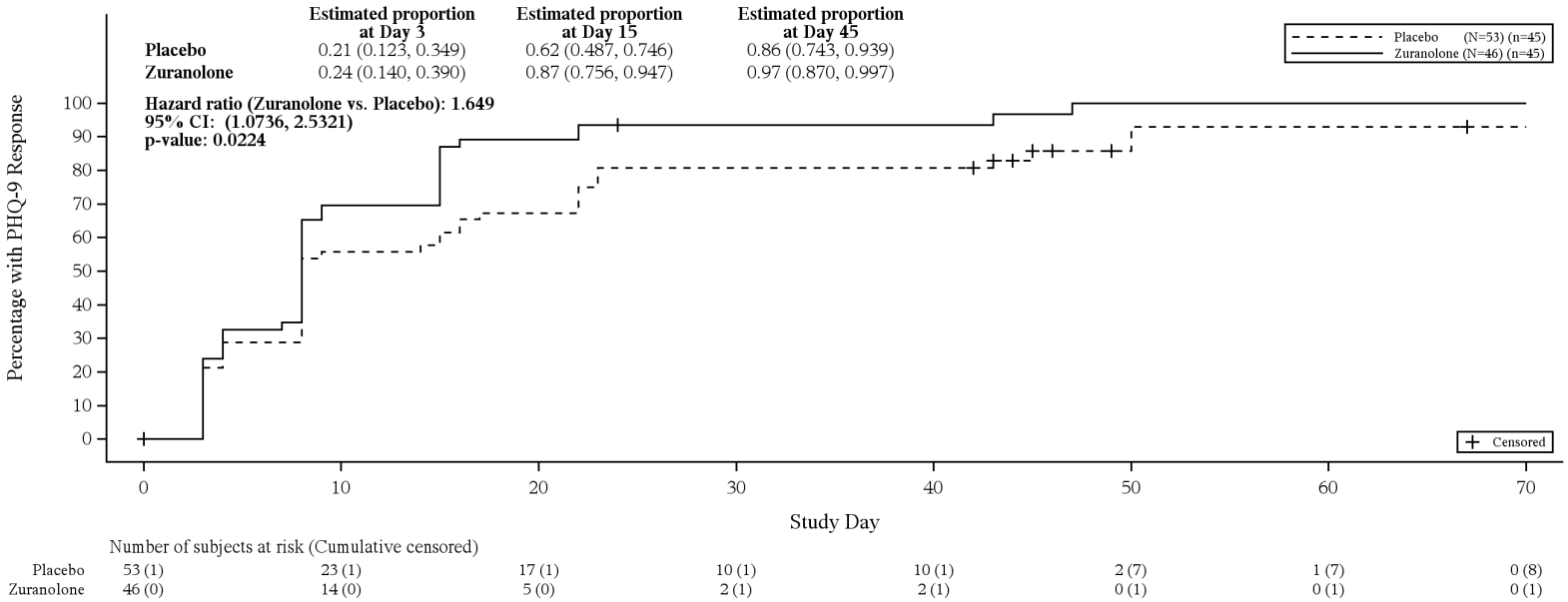
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-phq9-resp15-tte-201-by.sas:f-phq9-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

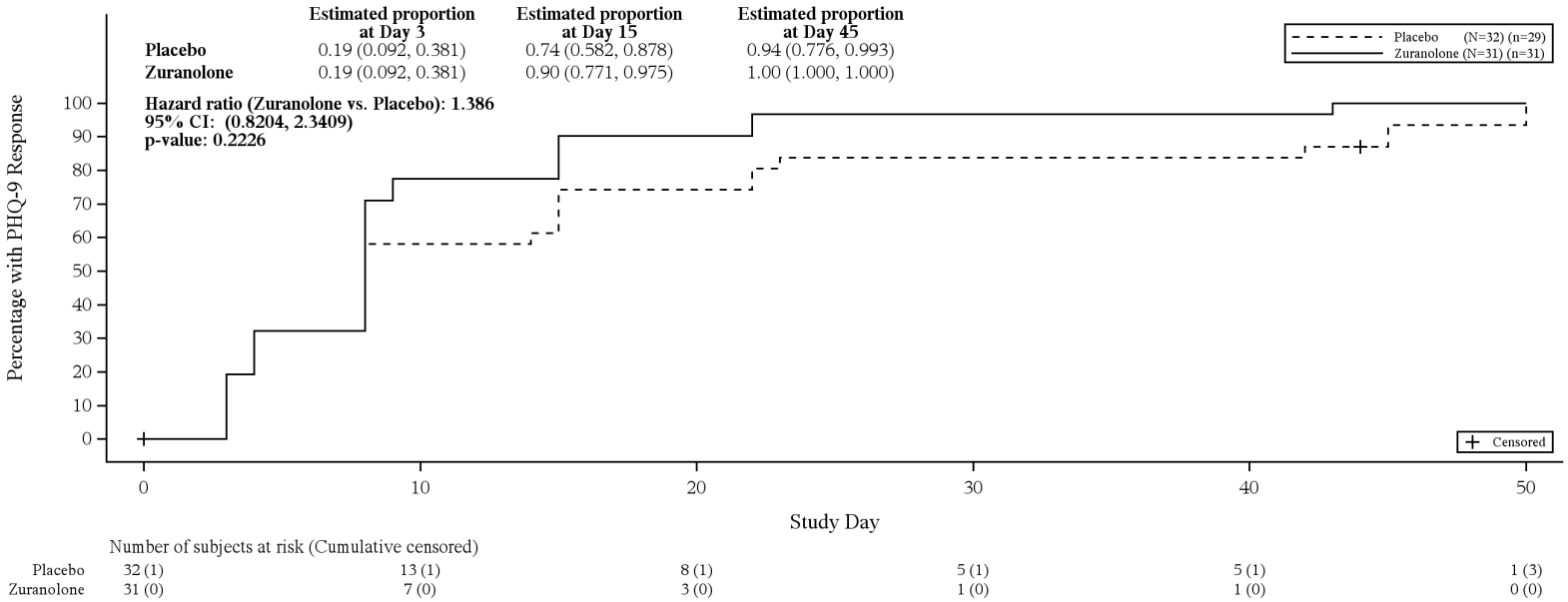
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Number of subjects at risk (Cumulative censored)

Placebo	32 (1)	13 (1)	8 (1)	5 (1)	5 (1)	1 (3)
Zuranolone	31 (0)	7 (0)	3 (0)	1 (0)	1 (0)	0 (0)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

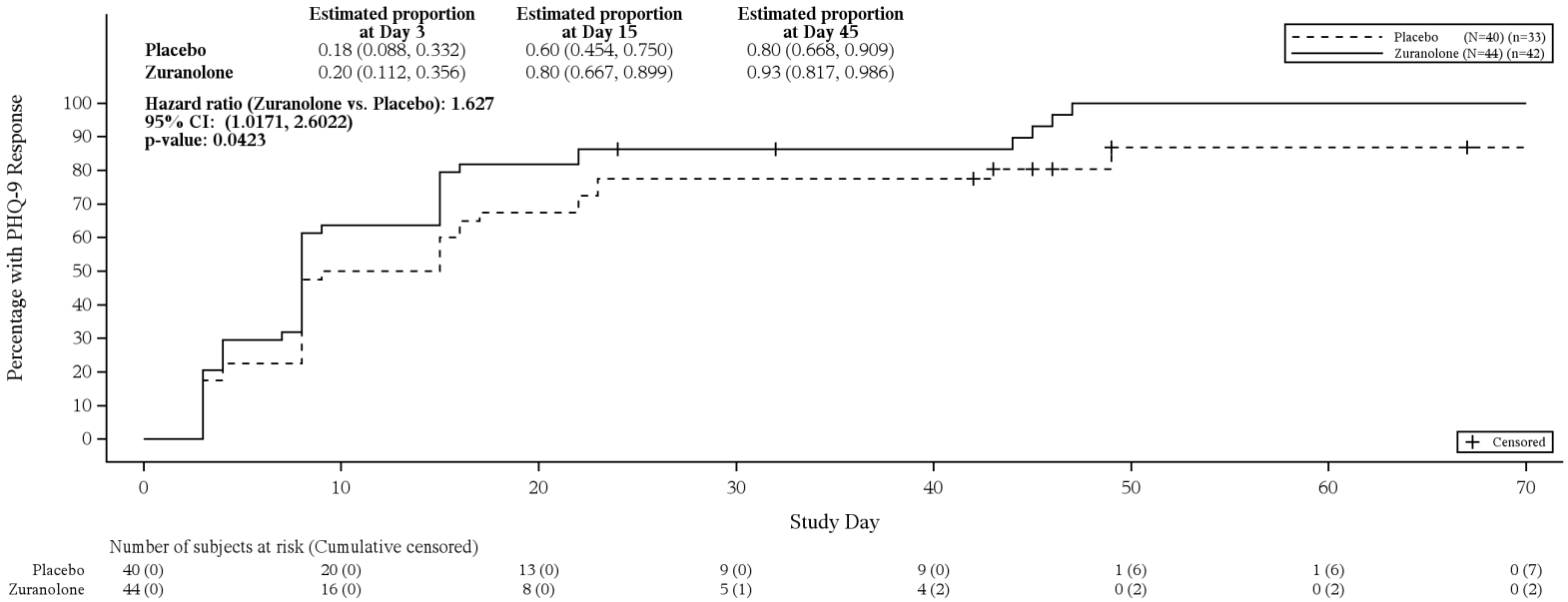
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Number of subjects at risk (Cumulative censored)

Placebo	40 (0)	20 (0)	13 (0)	9 (0)	9 (0)	1 (6)	1 (6)	0 (7)
Zuranolone	44 (0)	16 (0)	8 (0)	5 (1)	4 (2)	0 (2)	0 (2)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

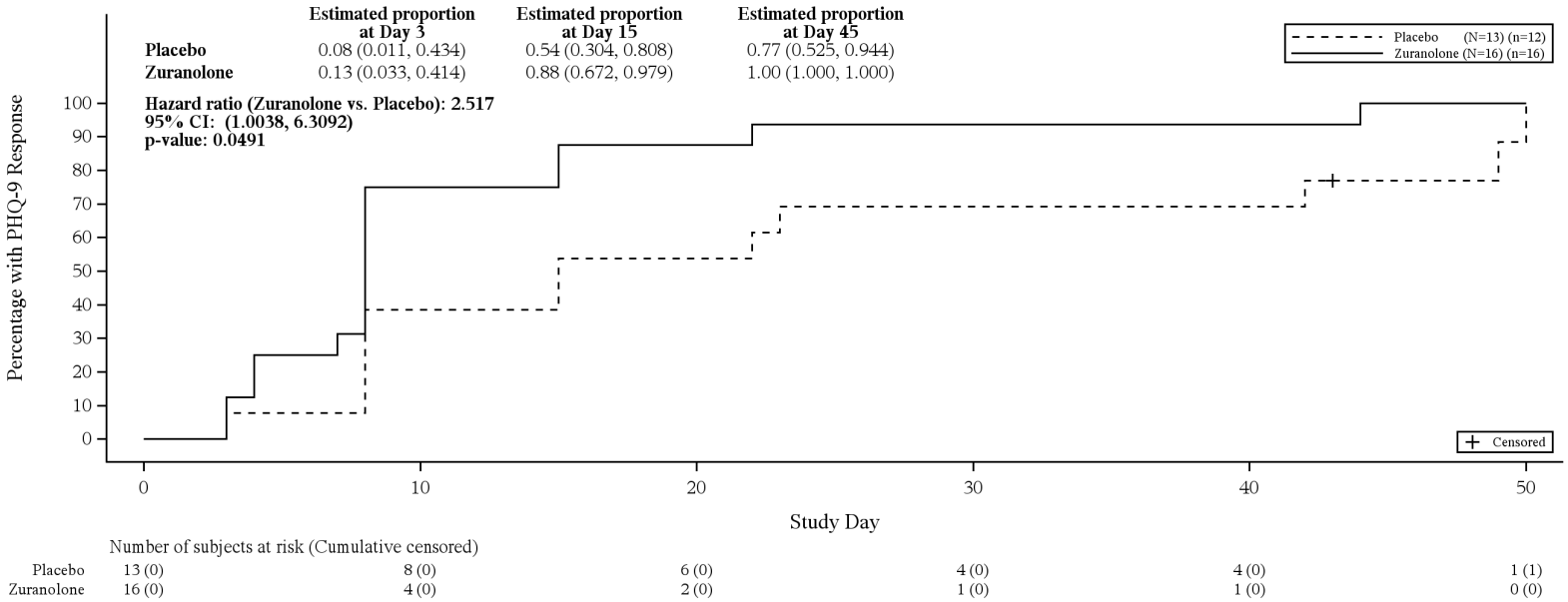
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	13 (0)	8 (0)	6 (0)	4 (0)	4 (0)	1 (1)
Zuranolone	16 (0)	4 (0)	2 (0)	1 (0)	1 (0)	0 (0)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

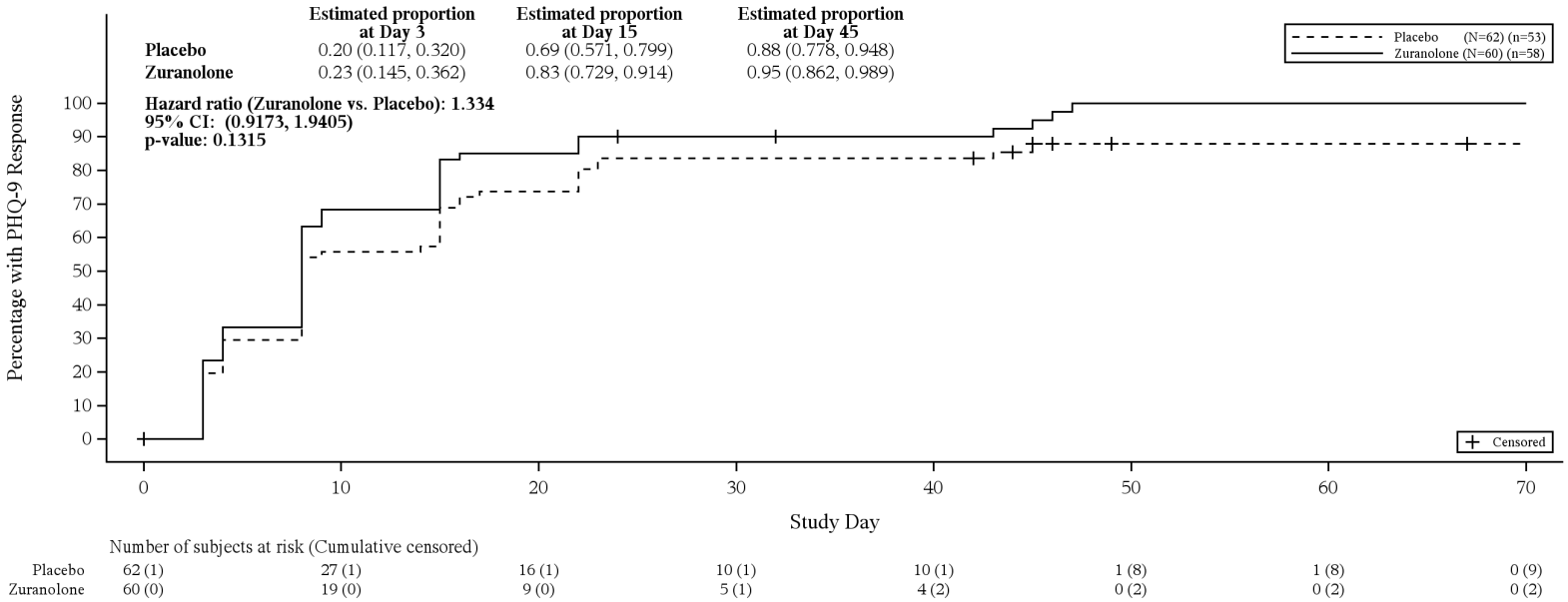
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Number of subjects at risk (Cumulative censored)

Placebo	62 (1)	27 (1)	16 (1)	10 (1)	10 (1)	1 (8)	1 (8)	0 (9)
Zuranolone	60 (0)	19 (0)	9 (0)	5 (1)	4 (2)	0 (2)	0 (2)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

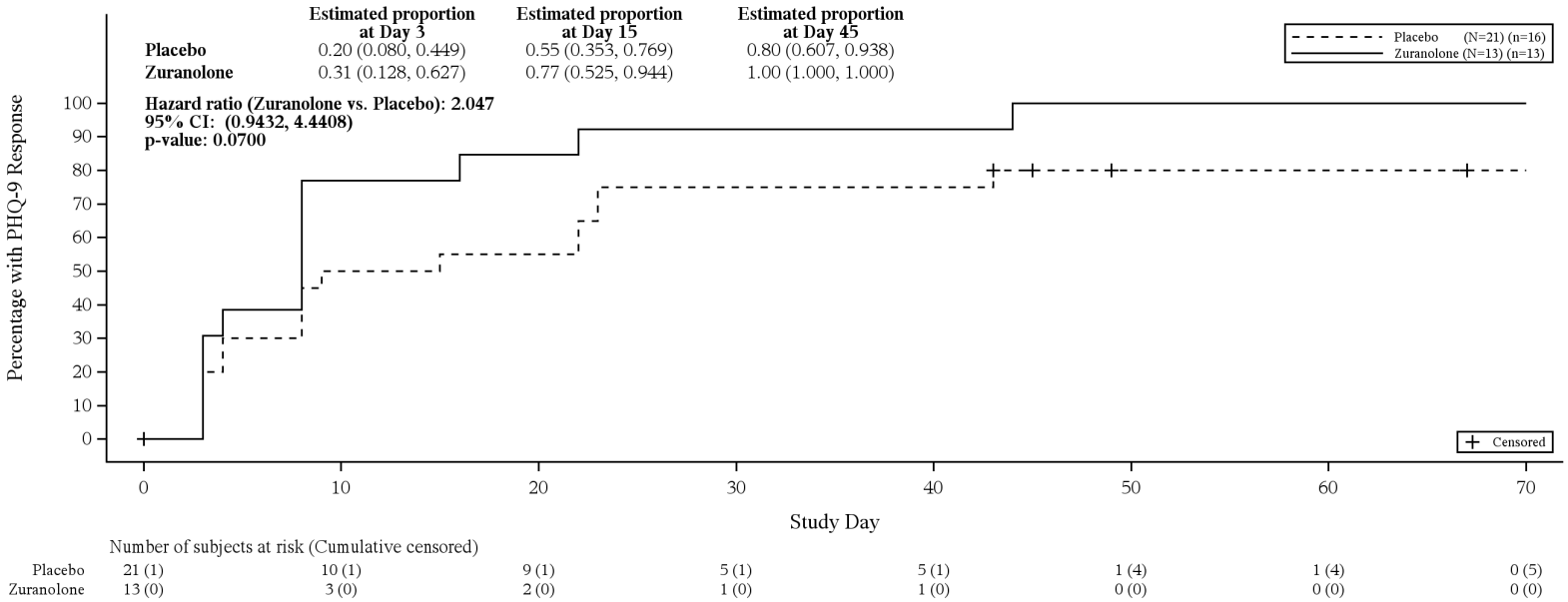
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

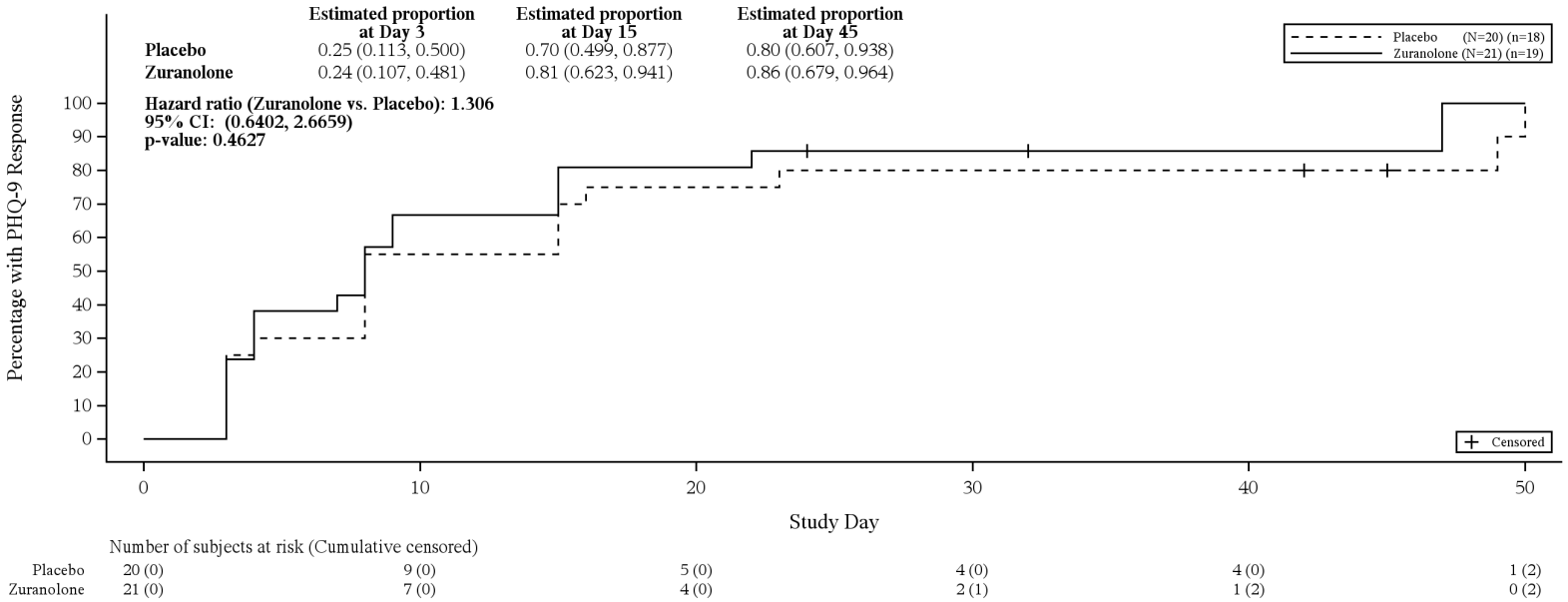
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Number of subjects at risk (Cumulative censored)

Placebo	20 (0)	9 (0)	5 (0)	4 (0)	4 (0)	1 (2)
Zuranolone	21 (0)	7 (0)	4 (0)	2 (1)	1 (2)	0 (2)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

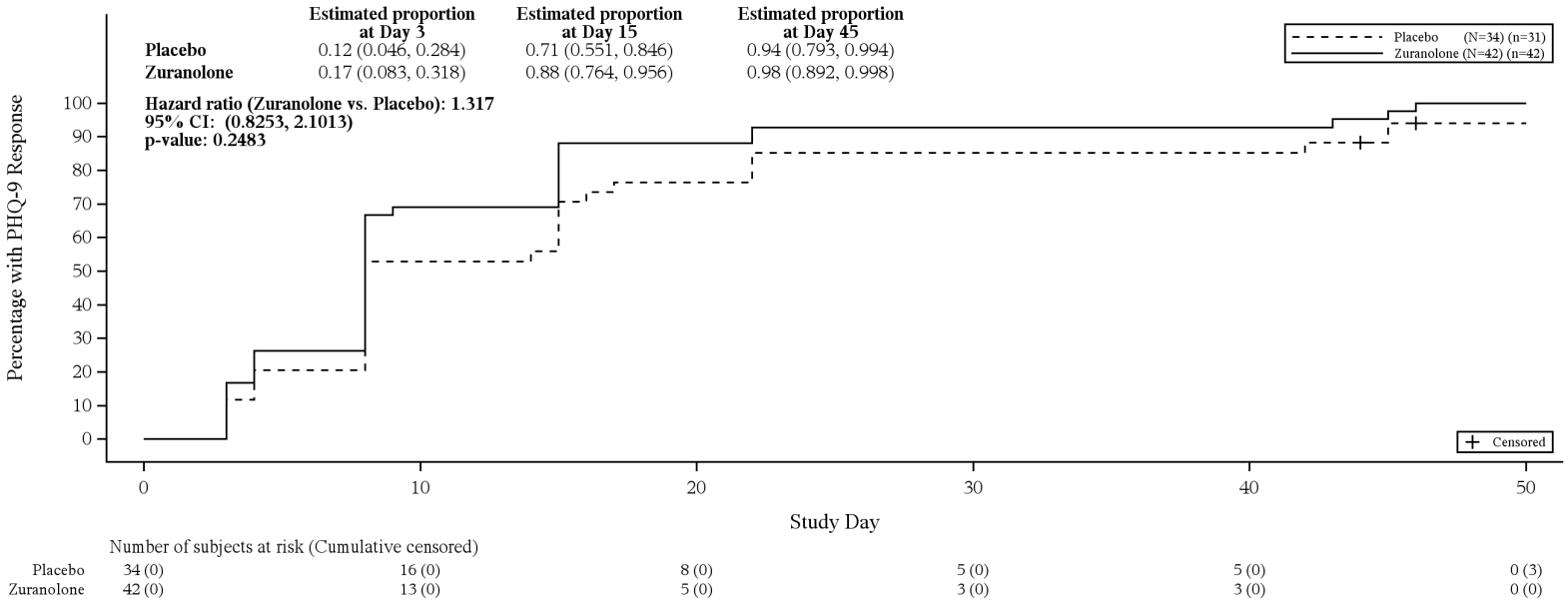
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

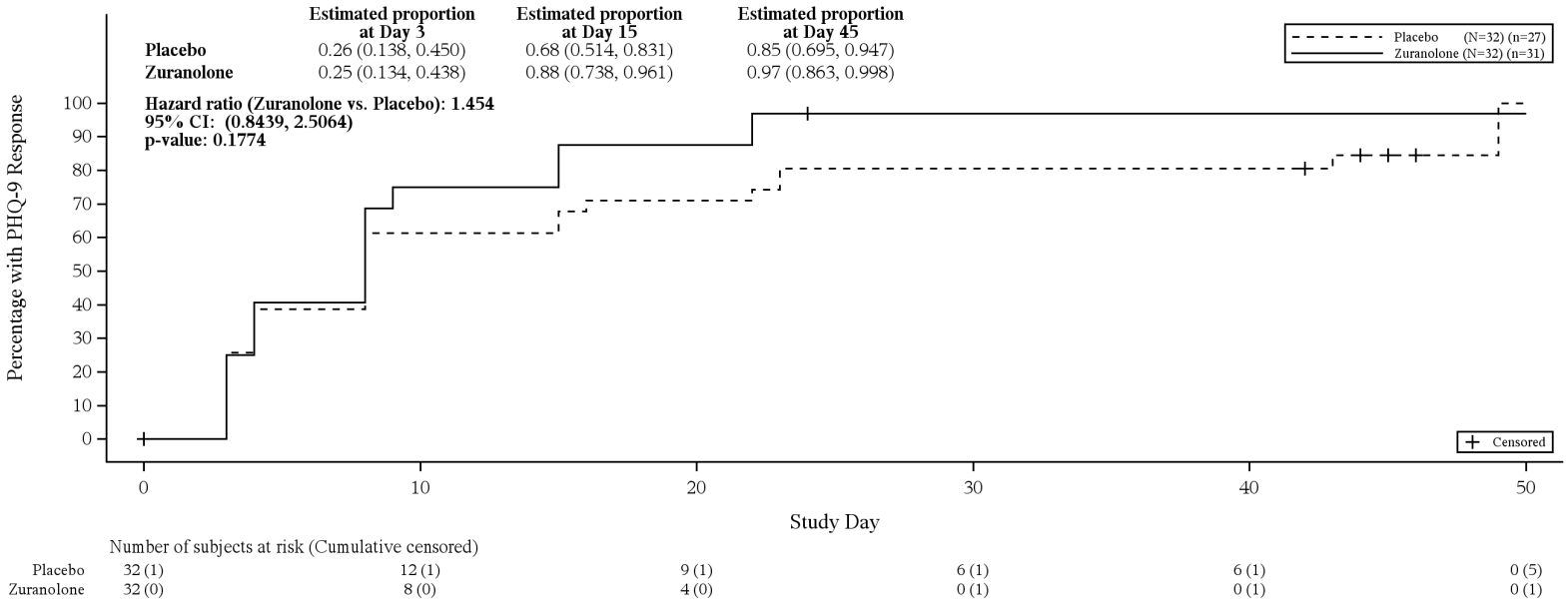
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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Number of subjects at risk (Cumulative censored)

Placebo	32 (1)	12 (1)	9 (1)	6 (1)	6 (1)	0 (5)
Zuranolone	32 (0)	8 (0)	4 (0)	0 (1)	0 (1)	0 (1)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

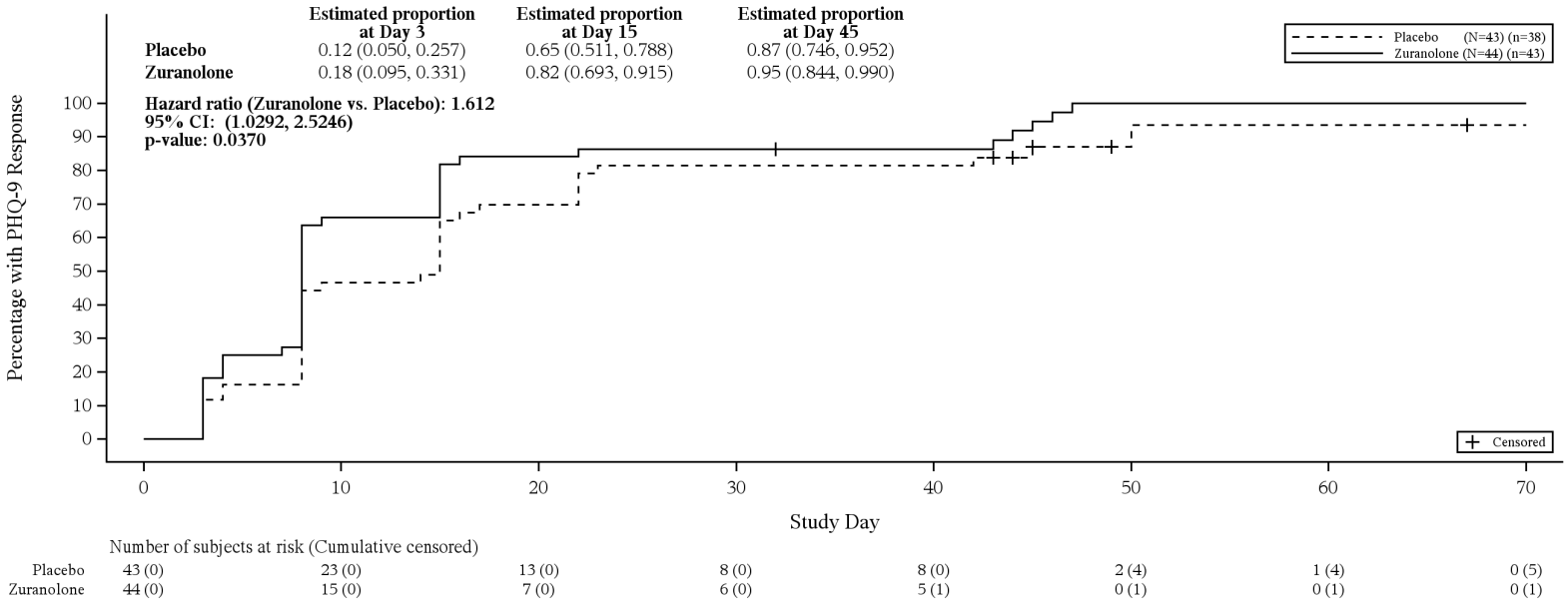
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

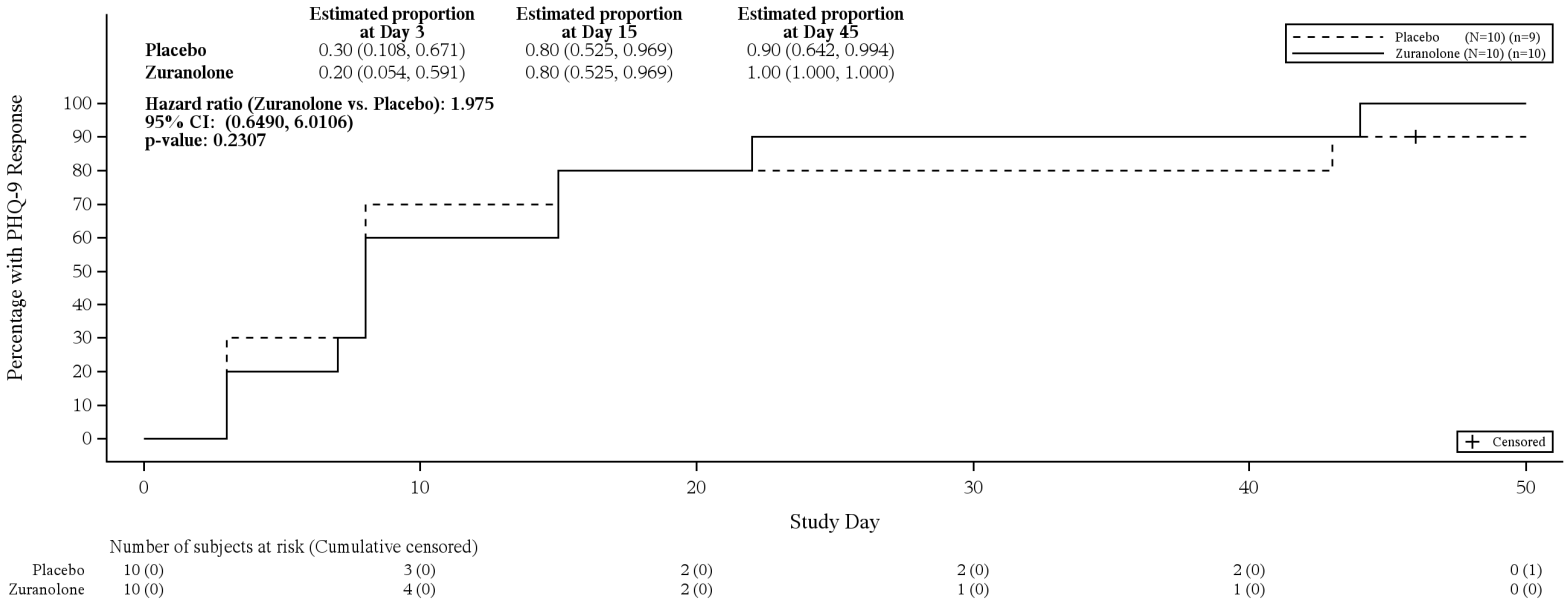
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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

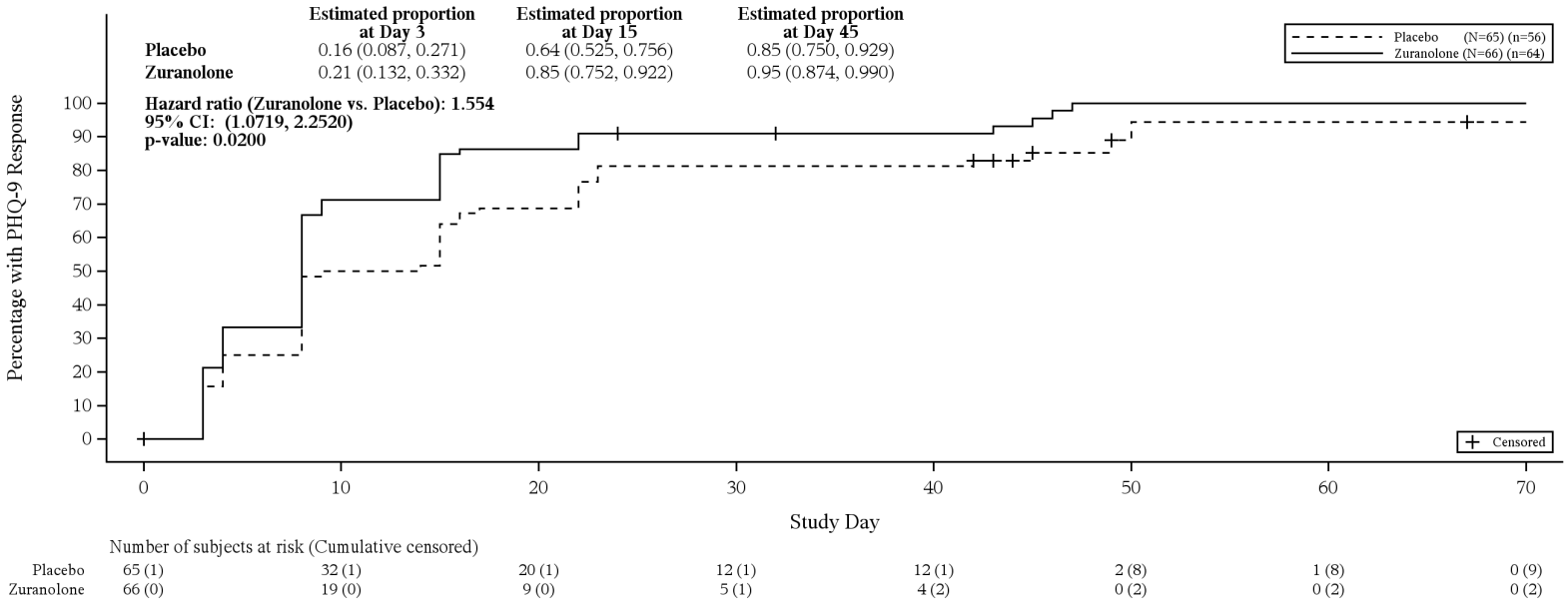
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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

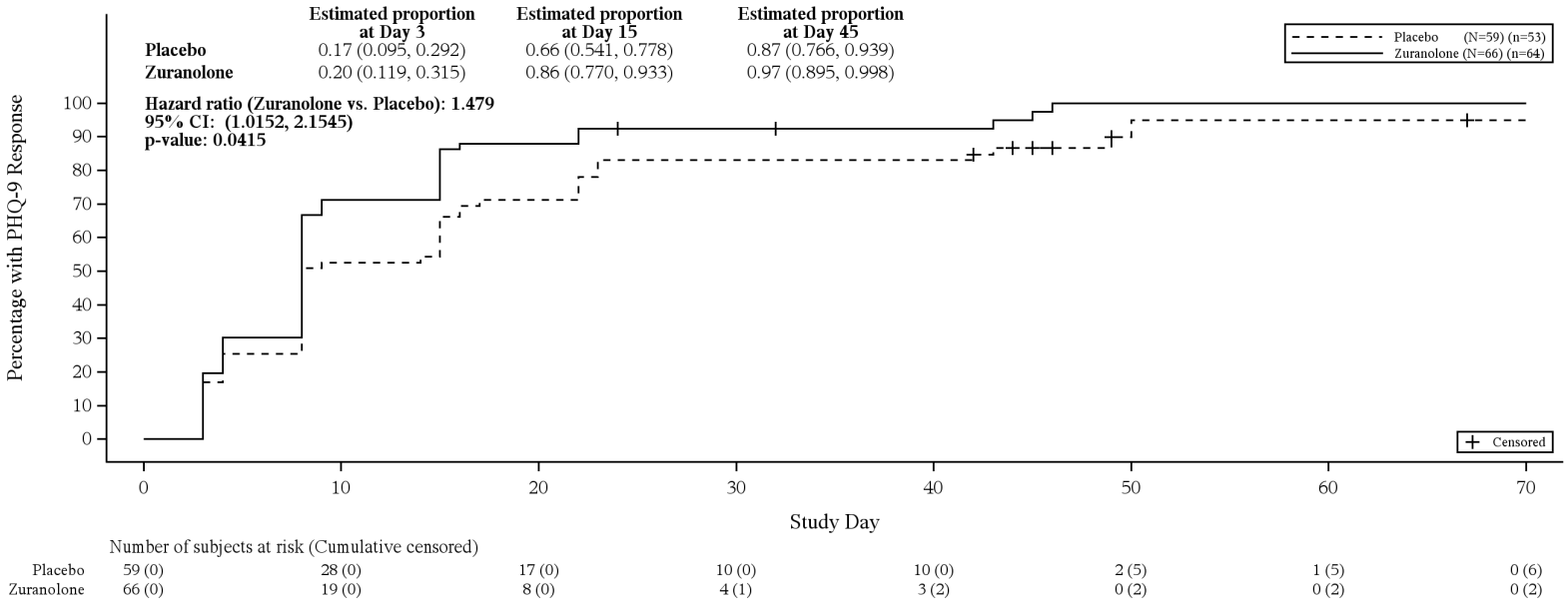
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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

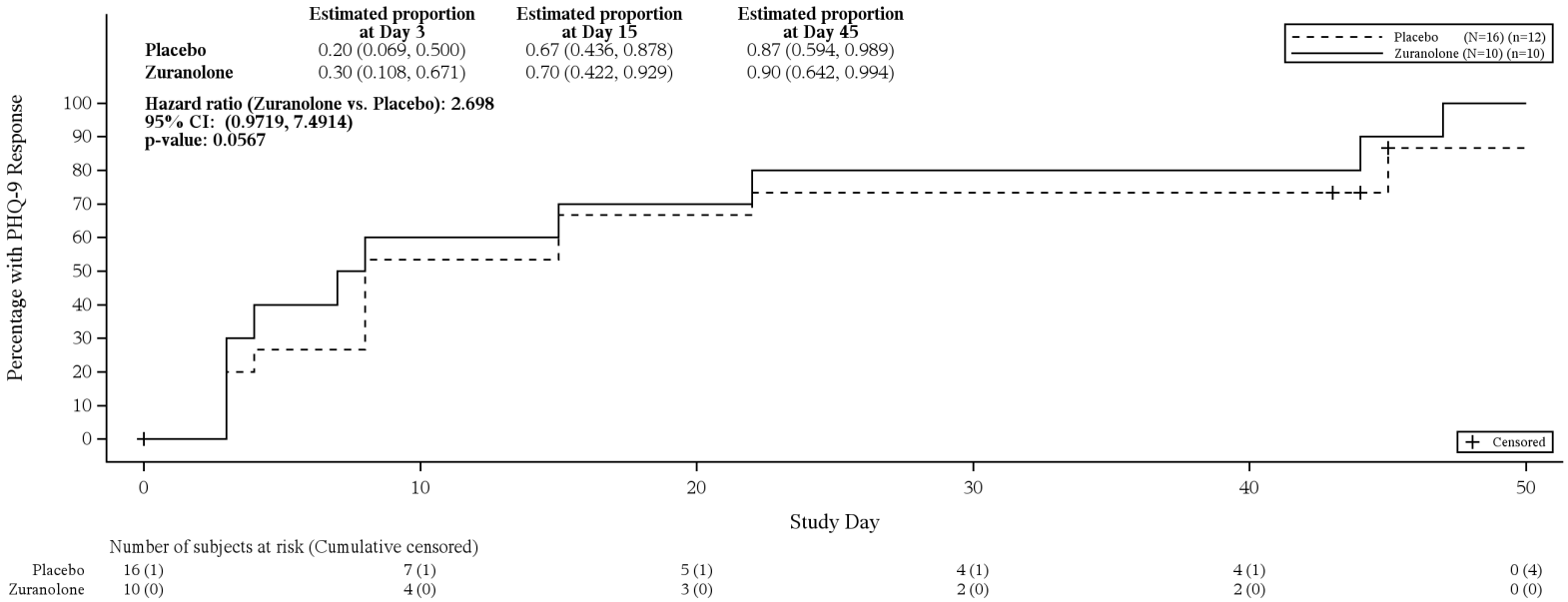
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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

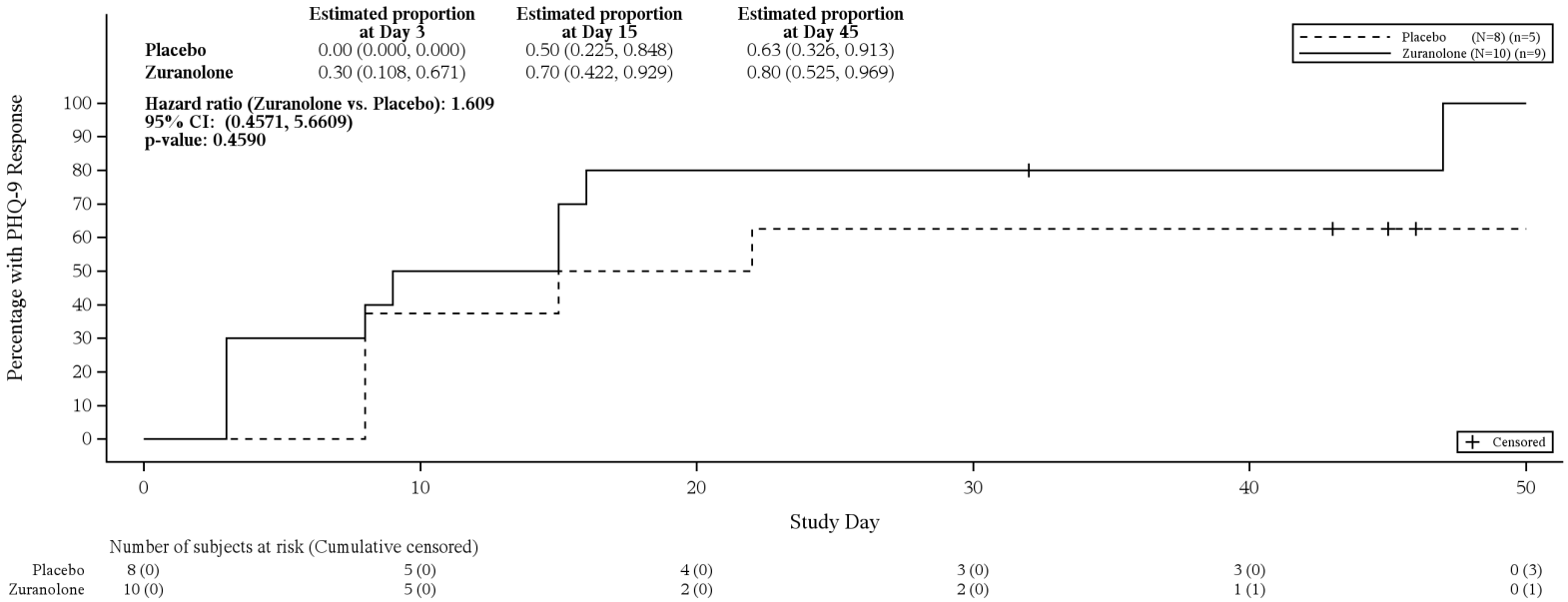
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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

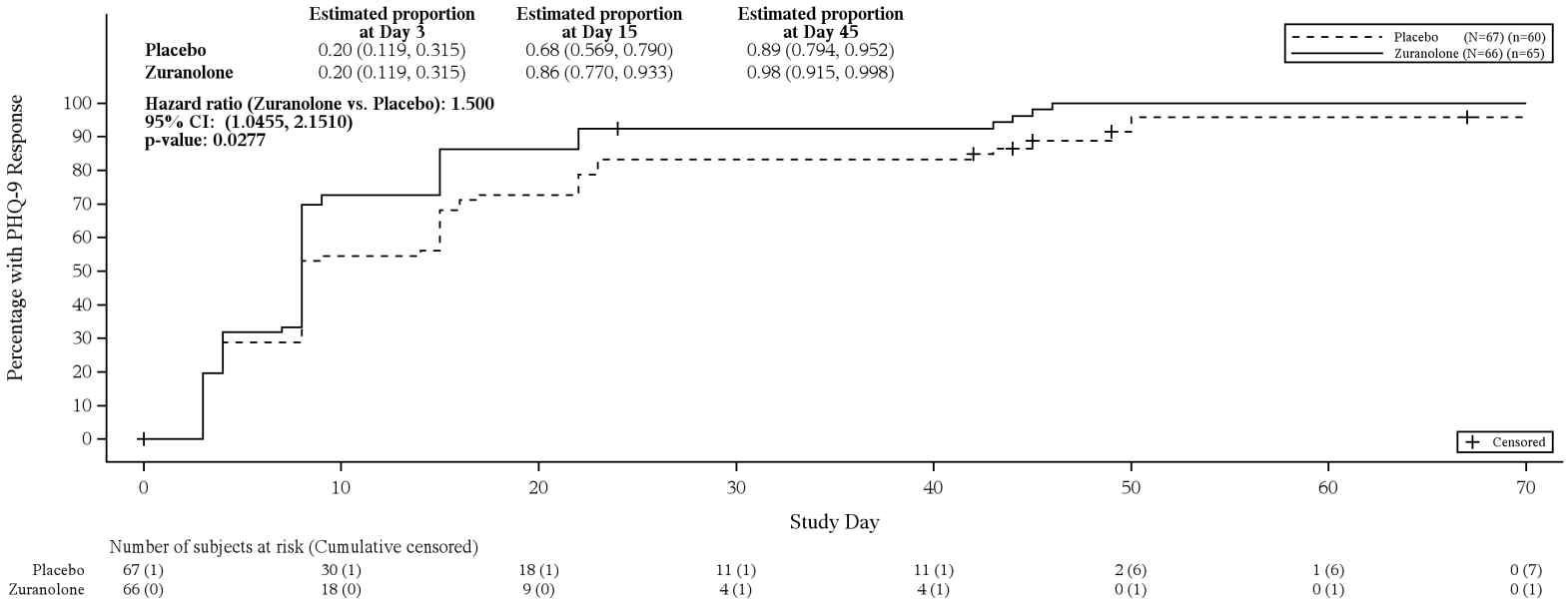
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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20



Number of subjects at risk (Cumulative censored)

Placebo	67 (1)	30 (1)	18 (1)	11 (1)	11 (1)	2 (6)	1 (6)	0 (7)
Zuranolone	66 (0)	18 (0)	9 (0)	4 (1)	4 (1)	0 (1)	0 (1)	0 (1)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: PHQ-9 response is defined as 4.05 points (15% of total scale range 0-27) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-phq9-resp15-tte-201-by.sas:f-phq9-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

4.4.3 Verschlechterung

4.4.3.1 Responder-Analysen

4.4.3.1 .1 ITT-Population

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with worsening, n (%) [2]	3 (4.0)	2 (2.6)
Number of subjects with missing evaluation, n (%)	3 (4.0)	4 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.66
95% CI for the RR		(0.113, 3.826)
p-value for RR		0.6411
OR - Odds Ratio (Zuranolone vs. Placebo)		0.65
95% CI for the OR		(0.105, 3.997)
p-value for OR		0.6408
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.071, 0.043)
p-value for ARR		0.6386

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a PHQ-9 worsening (4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-201-ovr.sas:t-phq9-wors15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 2 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with worsening, n (%) [2]	0	1 (1.3)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.96
95% CI for the RR		(0.123, 71.552)
p-value for RR		0.5041
OR - Odds Ratio (Zuranolone vs. Placebo)		3.00
95% CI for the OR		(0.120, 74.819)
p-value for OR		0.5032
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.023, 0.049)
p-value for ARR		0.4803

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a PHQ-9 worsening (4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-201-ovr.sas:t-phq9-wors15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 3 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with worsening, n (%) [2]	1 (1.3)	1 (1.3)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.99
95% CI for the RR		(0.063, 15.489)
p-value for RR		0.9925
OR - Odds Ratio (Zuranolone vs. Placebo)		0.99
95% CI for the OR		(0.061, 16.070)
p-value for OR		0.9925
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.037, 0.036)
p-value for ARR		0.9925

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a PHQ-9 worsening (4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-201-ovr.sas:t-phq9-wors15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 4 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with worsening, n (%) [2]	2 (2.7)	0
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.20
95% CI for the RR		(0.010, 4.044)
p-value for RR		0.2923
OR - Odds Ratio (Zuranolone vs. Placebo)		0.19
95% CI for the OR		(0.009, 4.070)
p-value for OR		0.2897
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.070, 0.018)
p-value for ARR		0.2388

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a PHQ-9 worsening (4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-201-ovr.sas:t-phq9-wors15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with worsening, n (%) [2]	2 (2.7)	0
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.20
95% CI for the RR		(0.010, 4.044)
p-value for RR		0.2923
OR - Odds Ratio (Zuranolone vs. Placebo)		0.19
95% CI for the OR		(0.009, 4.070)
p-value for OR		0.2897
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.070, 0.018)
p-value for ARR		0.2388

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.
[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a PHQ-9 worsening (4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline). Missing total score at the visit has been imputed as "no worsening". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-201-ovr.sas:t-phq9-wors15-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.4.3.1 .2 Subgruppen

4.4.3.1 .2 .1 Interaktionstest

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	1 (1.3)	1 (1.3)	
Number of subjects with response at Day 45, n (%)	2 (2.7)	0	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	1/25 (4.0)	1/17 (5.9)	
25 - 45, n / N (%)	0/50	0/59	
Day 45			
18 - 24, n / N (%)	2/25 (8.0)	0/17	
25 - 45, n / N (%)	0/50	0/59	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 worsening is defined as 4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-201-int.sas:t-phq9-wors15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			NA
Day 15			
<28, n / N (%)	1/22 (4.5)	0/30	
>=28, n / N (%)	0/53	1/46 (2.2)	
Day 45			
<28, n / N (%)	2/22 (9.1)	0/30	
>=28, n / N (%)	0/53	0/46	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	1/32 (3.1)	0/31	
White, n / N (%)	0/40	1/44 (2.3)	
Day 45			
Black or African American, n / N (%)	1/32 (3.1)	0/31	
White, n / N (%)	1/40 (2.5)	0/44	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 worsening is defined as 4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-201-int.sas:t-phq9-wors15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	1/62 (1.6)	1/60 (1.7)	
Day 45			
Yes, n / N (%)	0/13	0/16	
No, n / N (%)	2/62 (3.2)	0/60	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 worsening is defined as 4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-201-int.sas:t-phq9-wors15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			NA(a) NA(b) NA(c)
Day 15			
<=24.9, n / N (%)	0/21	0/13	
25-29.9, n / N (%)	0/20	0/21	
>=30, n / N (%)	1/34 (2.9)	1/42 (2.4)	
Day 45			
<=24.9, n / N (%)	1/21 (4.8)	0/13	
25-29.9, n / N (%)	0/20	0/21	
>=30, n / N (%)	1/34 (2.9)	0/42	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 worsening is defined as 4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-201-int.sas:t-phq9-wors15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	0/32	0/32	
Postpartum, n / N (%)	1/43 (2.3)	1/44 (2.3)	
Day 45			
3rd Trimester, n / N (%)	1/32 (3.1)	0/32	
Postpartum, n / N (%)	1/43 (2.3)	0/44	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	1/65 (1.5)	1/66 (1.5)	
Day 45			
Yes, n / N (%)	0/10	0/10	
No/Unknown, n / N (%)	2/65 (3.1)	0/66	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 worsening is defined as 4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-201-int.sas:t-phq9-wors15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	1/59 (1.7)	1/66 (1.5)	
Recurrent Episode, n / N (%)	0/16	0/10	
Day 45			
1st Episode, n / N (%)	1/59 (1.7)	0/66	
Recurrent Episode, n / N (%)	1/16 (6.3)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/8	0/10	
>=20, n / N (%)	1/67 (1.5)	1/66 (1.5)	
Day 45			
<20, n / N (%)	1/8 (12.5)	0/10	
>=20, n / N (%)	1/67 (1.5)	0/66	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 worsening is defined as 4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-201-int.sas:t-phq9-wors15-201-int-itta.rtf **Run Date:** 30JUL2025

4.4.3.1 .2 .2 Subgruppenanalysen

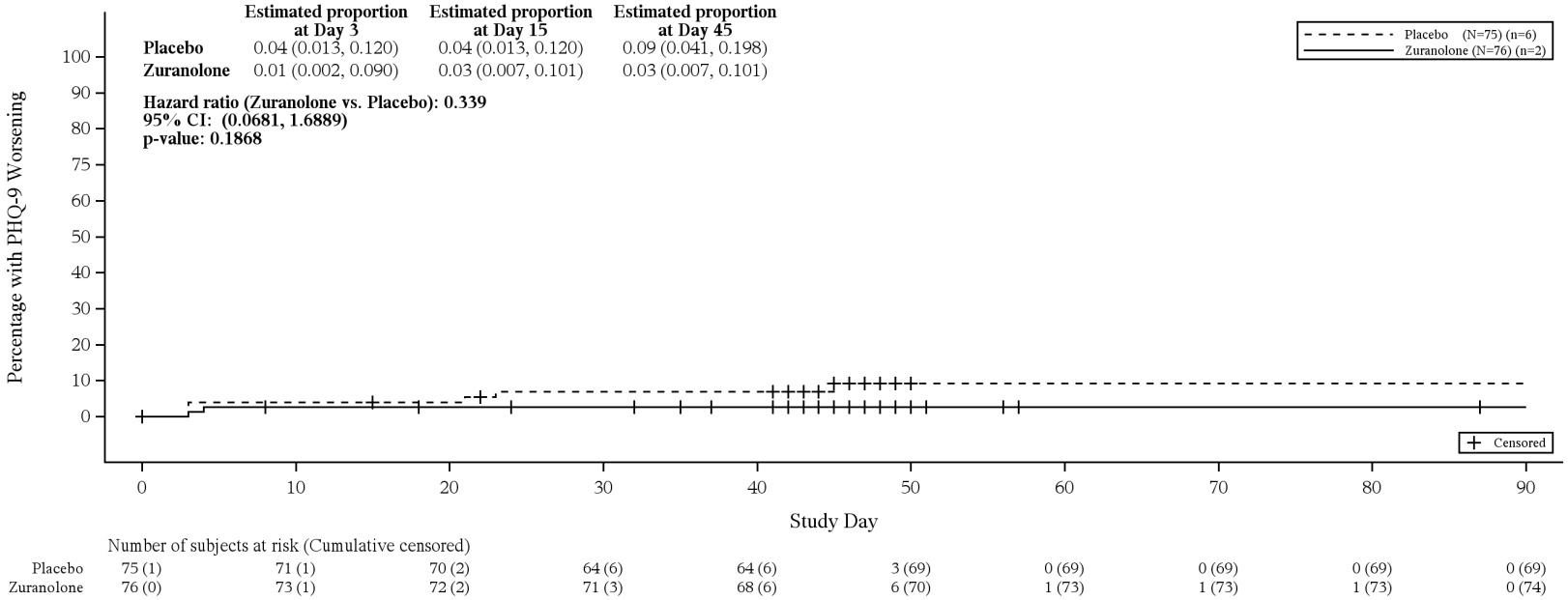
Nicht zutreffend.

4.4.3.2 TTE-Analysen

4.4.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with worsening.
NOTE 1: Subjects with non-missing PHQ-9 total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: PHQ-9 worsening is defined as 4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-phq9-wors15-tte-201-ovr.sas:f-phq9-wors15-tte-201-ovr-itta.rtf **Run Date:** 16DEC2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-201B - ITT population

Page: 1 of 1

	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	6 (8.0)	2 (2.6)
Time to first PHQ-9 worsening (days) [3]		
25th percentile - Q1 (95% CI)	NE (NE, NE)	NE (NE, NE)
50th percentile - median (95% CI)	NE (NE, NE)	NE (NE, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.339
95% CI for the HR		(0.0681 , 1.6889)
p-value for the HR		0.1868

NOTE 1: PHQ-9 worsening is defined as 4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing PHQ-9 total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a PHQ-9 worsening. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline PHQ-9 total score, and treatment.

Source: biib125/v_a/germany_amnog/t-phq9-wors15-tte-201-ovr.sas:t-phq9-wors15-tte-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.4.3.2 .2 Subgruppen

4.4.3.2 .2 .1 Interaktionstest

Summary of Time to First Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	6 (8.0)	2 (2.6)	
Age Group (years)			
18 - 24, n / N (%)	4/25 (16.0)	2/17 (11.8)	NA
25 - 45, n / N (%)	2/50 (4.0)	0/59	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	3/22 (13.6)	0/30	NA
>=28, n / N (%)	3/53 (5.7)	2/46 (4.3)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	3/32 (9.4)	0/31	NA
White, n / N (%)	2/40 (5.0)	2/44 (4.5)	
Antidepressant Use at Baseline			
Yes, n / N (%)	0/13	0/16	NA
No, n / N (%)	6/62 (9.7)	2/60 (3.3)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 worsening is defined as 4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-tte-201-int.sas:t-phq9-wors15-tte-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	2/21 (9.5)	0/13	NA(a)
25-29.9, n / N (%)	0/20	0/21	NA(b)
>=30, n / N (%)	4/34 (11.8)	2/42 (4.8)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	3/32 (9.4)	0/32	NA
Postpartum, n / N (%)	3/43 (7.0)	2/44 (4.5)	
Family History of PPD			
Yes, n / N (%)	1/10 (10.0)	0/10	NA
No/Unknown, n / N (%)	5/65 (7.7)	2/66 (3.0)	
History of PPD			
1st Episode, n / N (%)	4/59 (6.8)	2/66 (3.0)	NA
Recurrent Episode, n / N (%)	2/16 (12.5)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	1/8 (12.5)	0/10	NA
>=20, n / N (%)	5/67 (7.5)	2/66 (3.0)	

NOTE 1: NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: PHQ-9 worsening is defined as 4.05 points (15% of total scale range 0-27) or greater increase in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with worsening in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-phq9-wors15-tte-201-int.sas:t-phq9-wors15-tte-201-int-itta.rtf **Run Date:** 29JUL2025

4.4.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

4.4.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

4.5 HAMA

4.5.1 MMRM

Model-based Results on Change from Baseline in Hamilton Rating Scale for Anxiety (HAM-A) Total Score: 217-PPD-201B - ITT population

Page: 1 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 3		
n	74	74
LS Mean (SE)	-8.82 (0.912)	-11.94 (0.908)
95% CI for the LS Mean	-10.62, -7.02	-13.73, -10.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.12 (1.289)
95% CI for the LS Mean		-5.66, -0.57
p-value		0.0169
Hedges' g (Zuranolone vs. Placebo)		-0.395
95% CI for Hedges' g		-0.7206, -0.0699
Day 8		
n	74	75
LS Mean (SE)	-11.60 (0.936)	-16.03 (0.928)
95% CI for the LS Mean	-13.45, -9.75	-17.86, -14.20
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.43 (1.321)
95% CI for the LS Mean		-7.04, -1.82
p-value		0.0010
Hedges' g (Zuranolone vs. Placebo)		-0.547
95% CI for Hedges' g		-0.8737, -0.2196

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The HAM-A total score was calculated as the sum of the 14 individual item scores. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-hama-mmrm-201-ovr.sas:t-hama-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Hamilton Rating Scale for Anxiety (HAM-A) Total Score: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	-12.63 (0.997)	-16.53 (0.987)
95% CI for the LS Mean	-14.60, -10.66	-18.48, -14.58
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.90 (1.406)
95% CI for the LS Mean		-6.68, -1.12
p-value		0.0063
Hedges' g (Zuranolone vs. Placebo)		-0.455
95% CI for Hedges' g		-0.7827, -0.1277
Day 21		
n	73	74
LS Mean (SE)	-13.03 (0.975)	-16.53 (0.966)
95% CI for the LS Mean	-14.96, -11.10	-18.44, -14.62
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.50 (1.375)
95% CI for the LS Mean		-6.22, -0.79
p-value		0.0119
Hedges' g (Zuranolone vs. Placebo)		-0.418
95% CI for Hedges' g		-0.7450, -0.0914

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The HAM-A total score was calculated as the sum of the 14 individual item scores. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-hama-mmrm-201-ovr.sas:t-hama-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Hamilton Rating Scale for Anxiety (HAM-A) Total Score: 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 45		
n	69	73
LS Mean (SE)	-13.54 (0.914)	-18.51 (0.898)
95% CI for the LS Mean	-15.35, -11.74	-20.29, -16.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.97 (1.284)
95% CI for the LS Mean		-7.51, -2.43
p-value		0.0002
Hedges' g (Zuranolone vs. Placebo)		-0.646
95% CI for Hedges' g		-0.9840, -0.3088

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: The HAM-A total score was calculated as the sum of the 14 individual item scores. A negative change indicates improvement.
Source: biib125/v_a/germany_amnog/t-hama-mmrm-201-ovr.sas:t-hama-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.5.2 Ansprechen

4.5.2.1 Responder-Analysen

4.5.2.1 .1 ITT-Population

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with a response, n (%) [2]	35 (46.7)	40 (52.6)
Number of subjects with missing evaluation, n (%)	1 (1.3)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.150
95% CI for the RR		(0.841, 1.574)
p-value for RR		0.3820
OR - Odds Ratio (Zuranolone vs. Placebo)		1.348
95% CI for the OR		(0.716, 2.538)
p-value for OR		0.3545
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.
[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hama-resp15-201-ovr.sas:t-hama-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 2 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with a response, n (%) [2]	48 (64.0)	59 (77.6)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.237
95% CI for the RR		(1.009, 1.517)
p-value for RR		0.0410
OR - Odds Ratio (Zuranolone vs. Placebo)		2.150
95% CI for the OR		(1.052, 4.395)
p-value for OR		0.0359
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-ovr.sas:t-hama-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with a response, n (%) [2]	48 (64.0)	59 (77.6)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.237
95% CI for the RR		(1.006, 1.522)
p-value for RR		0.0442
OR - Odds Ratio (Zuranolone vs. Placebo)		2.152
95% CI for the OR		(1.038, 4.462)
p-value for OR		0.0394
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-ovr.sas:t-hama-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with a response, n (%) [2]	49 (65.3)	57 (75.0)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.171
95% CI for the RR		(0.950, 1.442)
p-value for RR		0.1389
OR - Odds Ratio (Zuranolone vs. Placebo)		1.742
95% CI for the OR		(0.850, 3.570)
p-value for OR		0.1294
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-ovr.sas:t-hama-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	50 (66.7)	62 (81.6)
Number of subjects with missing evaluation, n (%)	6 (8.0)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.248
95% CI for the RR		(1.033, 1.507)
p-value for RR		0.0214
OR - Odds Ratio (Zuranolone vs. Placebo)		2.466
95% CI for the OR		(1.167, 5.212)
p-value for OR		0.0181
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-ovr.sas:t-hama-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.5.2.1 .2 Subgruppen

4.5.2.1 .2 .1 Interaktionstest

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	48 (64.0)	59 (77.6)	
Number of subjects with response at Day 45, n (%)	50 (66.7)	62 (81.6)	
Age Group (years)			0.3279
Day 15			
18 - 24, n / N (%)	15/25 (60.0)	13/17 (76.5)	
25 - 45, n / N (%)	33/50 (66.0)	46/59 (78.0)	
Day 45			
18 - 24, n / N (%)	16/25 (64.0)	14/17 (82.4)	
25 - 45, n / N (%)	34/50 (68.0)	48/59 (81.4)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hama-resp15-201-int.sas:t-hama-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.0363
Day 15			
<28, n / N (%)	15/22 (68.2)	21/30 (70.0)	
>=28, n / N (%)	33/53 (62.3)	38/46 (82.6)	
Day 45			
<28, n / N (%)	18/22 (81.8)	24/30 (80.0)	
>=28, n / N (%)	32/53 (60.4)	38/46 (82.6)	
Race Group (Black or African American, White)			0.2299
Day 15			
Black or African American, n / N (%)	21/32 (65.6)	23/31 (74.2)	
White, n / N (%)	25/40 (62.5)	35/44 (79.5)	
Day 45			
Black or African American, n / N (%)	23/32 (71.9)	23/31 (74.2)	
White, n / N (%)	25/40 (62.5)	38/44 (86.4)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hama-resp15-201-int.sas:t-hama-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.6816
Day 15			
Yes, n / N (%)	9/13 (69.2)	13/16 (81.3)	
No, n / N (%)	39/62 (62.9)	46/60 (76.7)	
Day 45			
Yes, n / N (%)	7/13 (53.8)	14/16 (87.5)	
No, n / N (%)	43/62 (69.4)	48/60 (80.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hama-resp15-201-int.sas:t-hama-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.2587(a) 0.0755(b) 0.0016(c)
Day 15			
<=24.9, n / N (%)	10/21 (47.6)	10/13 (76.9)	
25-29.9, n / N (%)	11/20 (55.0)	19/21 (90.5)	
>=30, n / N (%)	27/34 (79.4)	30/42 (71.4)	
Day 45			
<=24.9, n / N (%)	10/21 (47.6)	12/13 (92.3)	
25-29.9, n / N (%)	15/20 (75.0)	18/21 (85.7)	
>=30, n / N (%)	25/34 (73.5)	32/42 (76.2)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hama-resp15-201-int.sas:t-hama-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.7167
Day 15			
3rd Trimester, n / N (%)	20/32 (62.5)	26/32 (81.3)	
Postpartum, n / N (%)	28/43 (65.1)	33/44 (75.0)	
Day 45			
3rd Trimester, n / N (%)	22/32 (68.8)	27/32 (84.4)	
Postpartum, n / N (%)	28/43 (65.1)	35/44 (79.5)	
Family History of PPD			0.4386
Day 15			
Yes, n / N (%)	7/10 (70.0)	9/10 (90.0)	
No/Unknown, n / N (%)	41/65 (63.1)	50/66 (75.8)	
Day 45			
Yes, n / N (%)	7/10 (70.0)	9/10 (90.0)	
No/Unknown, n / N (%)	43/65 (66.2)	53/66 (80.3)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hama-resp15-201-int.sas:t-hama-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.2297
Day 15			
1st Episode, n / N (%)	41/59 (69.5)	52/66 (78.8)	
Recurrent Episode, n / N (%)	7/16 (43.8)	7/10 (70.0)	
Day 45			
1st Episode, n / N (%)	41/59 (69.5)	54/66 (81.8)	
Recurrent Episode, n / N (%)	9/16 (56.3)	8/10 (80.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	4/8 (50.0)	8/10 (80.0)	
>=20, n / N (%)	44/67 (65.7)	51/66 (77.3)	
Day 45			
<20, n / N (%)	4/8 (50.0)	5/10 (50.0)	
>=20, n / N (%)	46/67 (68.7)	57/66 (86.4)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hama-resp15-201-int.sas:t-hama-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

4.5.2.1 .2 .2 Subgruppenanalysen

4.5.2.1 .2 .2 .1 Alter

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 1 of 6

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 3		
Number of subjects with a response, n (%) [2]	13 (52.0)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.407
95% CI for the RR		(0.895, 2.210)
p-value for RR		0.1391
Day 8		
Number of subjects with a response, n (%) [2]	15 (60.0)	16 (94.1)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.500
95% CI for the RR		(1.053, 2.137)
p-value for RR		0.0246

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 15		
Number of subjects with a response, n (%) [2]	15 (60.0)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.219
95% CI for the RR		(0.799, 1.861)
p-value for RR		0.3586
Day 21		
Number of subjects with a response, n (%) [2]	15 (60.0)	14 (82.4)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.313
95% CI for the RR		(0.889, 1.939)
p-value for RR		0.1712

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 45		
Number of subjects with a response, n (%) [2]	16 (64.0)	14 (82.4)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.231
95% CI for the RR		(0.868, 1.746)
p-value for RR		0.2442

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 3		
Number of subjects with a response, n (%) [2]	22 (44.0)	27 (45.8)
Number of subjects with missing evaluation, n (%)	1 (2.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.060
95% CI for the RR		(0.703, 1.598)
p-value for RR		0.7800
Day 8		
Number of subjects with a response, n (%) [2]	33 (66.0)	43 (72.9)
Number of subjects with missing evaluation, n (%)	1 (2.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.126
95% CI for the RR		(0.878, 1.443)
p-value for RR		0.3496

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 15		
Number of subjects with a response, n (%) [2]	33 (66.0)	46 (78.0)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.204
95% CI for the RR		(0.948, 1.529)
p-value for RR		0.1272
Day 21		
Number of subjects with a response, n (%) [2]	34 (68.0)	43 (72.9)
Number of subjects with missing evaluation, n (%)	2 (4.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.093
95% CI for the RR		(0.855, 1.396)
p-value for RR		0.4784

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 6 of 6

Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 45		
Number of subjects with a response, n (%) [2]	34 (68.0)	48 (81.4)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.220
95% CI for the RR		(0.976, 1.524)
p-value for RR		0.0810

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.5.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 3		
Number of subjects with a response, n (%) [2]	10 (45.5)	13 (43.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.965
95% CI for the RR		(0.530, 1.759)
p-value for RR		0.9082
Day 8		
Number of subjects with a response, n (%) [2]	16 (72.7)	19 (63.3)
Number of subjects with missing evaluation, n (%)	0	1 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.882
95% CI for the RR		(0.614, 1.267)
p-value for RR		0.4967

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 15		
Number of subjects with a response, n (%) [2]	15 (68.2)	21 (70.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.040
95% CI for the RR		(0.725, 1.490)
p-value for RR		0.8326
Day 21		
Number of subjects with a response, n (%) [2]	16 (72.7)	19 (63.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.882
95% CI for the RR		(0.599, 1.298)
p-value for RR		0.5240

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 45		
Number of subjects with a response, n (%) [2]	18 (81.8)	24 (80.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.990
95% CI for the RR		(0.773, 1.269)
p-value for RR		0.9371

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 3		
Number of subjects with a response, n (%) [2]	25 (47.2)	27 (58.7)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.257
95% CI for the RR		(0.871, 1.815)
p-value for RR		0.2213
Day 8		
Number of subjects with a response, n (%) [2]	32 (60.4)	40 (87.0)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.455
95% CI for the RR		(1.142, 1.854)
p-value for RR		0.0024

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 15		
Number of subjects with a response, n (%) [2]	33 (62.3)	38 (82.6)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.341
95% CI for the RR		(1.046, 1.718)
p-value for RR		0.0205
Day 21		
Number of subjects with a response, n (%) [2]	33 (62.3)	38 (82.6)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.341
95% CI for the RR		(1.048, 1.715)
p-value for RR		0.0197

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 45		
Number of subjects with a response, n (%) [2]	32 (60.4)	38 (82.6)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.383
95% CI for the RR		(1.076, 1.777)
p-value for RR		0.0113

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.5.2.1 .2 .2 .3 Abstammung

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 3		
Number of subjects with a response, n (%) [2]	16 (50.0)	14 (45.2)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.964
95% CI for the RR		(0.586, 1.586)
p-value for RR		0.8858
Day 8		
Number of subjects with a response, n (%) [2]	19 (59.4)	21 (67.7)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.218
95% CI for the RR		(0.852, 1.741)
p-value for RR		0.2794

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 15		
Number of subjects with a response, n (%) [2]	21 (65.6)	23 (74.2)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.207
95% CI for the RR		(0.875, 1.665)
p-value for RR		0.2520
Day 21		
Number of subjects with a response, n (%) [2]	23 (71.9)	19 (61.3)
Number of subjects with missing evaluation, n (%)	1 (3.1)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.910
95% CI for the RR		(0.637, 1.300)
p-value for RR		0.6051

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 45		
Number of subjects with a response, n (%) [2]	23 (71.9)	23 (74.2)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.102
95% CI for the RR		(0.820, 1.480)
p-value for RR		0.5192

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 3		
Number of subjects with a response, n (%) [2]	18 (45.0)	25 (56.8)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.256
95% CI for the RR		(0.827, 1.907)
p-value for RR		0.2855
Day 8		
Number of subjects with a response, n (%) [2]	26 (65.0)	37 (84.1)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.287
95% CI for the RR		(0.991, 1.670)
p-value for RR		0.0580

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	25 (62.5)	35 (79.5)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.266
95% CI for the RR		(0.955, 1.677)
p-value for RR		0.1011
Day 21		
Number of subjects with a response, n (%) [2]	25 (62.5)	38 (86.4)
Number of subjects with missing evaluation, n (%)	1 (2.5)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.374
95% CI for the RR		(1.051, 1.797)
p-value for RR		0.0202

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	25 (62.5)	38 (86.4)
Number of subjects with missing evaluation, n (%)	4 (10.0)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.374
95% CI for the RR		(1.056, 1.788)
p-value for RR		0.0179

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.5.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 6

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 3		
Number of subjects with a response, n (%) [2]	6 (46.2)	7 (43.8)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.940
95% CI for the RR		(0.417, 2.122)
p-value for RR		0.8824
Day 8		
Number of subjects with a response, n (%) [2]	8 (61.5)	13 (81.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.310
95% CI for the RR		(0.795, 2.158)
p-value for RR		0.2894

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 15		
Number of subjects with a response, n (%) [2]	9 (69.2)	13 (81.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.164
95% CI for the RR		(0.747, 1.815)
p-value for RR		0.5017
Day 21		
Number of subjects with a response, n (%) [2]	7 (53.8)	14 (87.5)
Number of subjects with missing evaluation, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.612
95% CI for the RR		(0.928, 2.799)
p-value for RR		0.0898

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 45		
Number of subjects with a response, n (%) [2]	7 (53.8)	14 (87.5)
Number of subjects with missing evaluation, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.612
95% CI for the RR		(0.945, 2.751)
p-value for RR		0.0798

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 3		
Number of subjects with a response, n (%) [2]	29 (46.8)	33 (55.0)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.210
95% CI for the RR		(0.863, 1.696)
p-value for RR		0.2694
Day 8		
Number of subjects with a response, n (%) [2]	40 (64.5)	46 (76.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.222
95% CI for the RR		(0.976, 1.532)
p-value for RR		0.0808

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 15		
Number of subjects with a response, n (%) [2]	39 (62.9)	46 (76.7)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.254
95% CI for the RR		(0.992, 1.585)
p-value for RR		0.0587
Day 21		
Number of subjects with a response, n (%) [2]	42 (67.7)	43 (71.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.088
95% CI for the RR		(0.864, 1.371)
p-value for RR		0.4731

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 45		
Number of subjects with a response, n (%) [2]	43 (69.4)	48 (80.0)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.187
95% CI for the RR		(0.968, 1.454)
p-value for RR		0.0992

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.5.2.1 .2 .2 .5 BMI

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 3		
Number of subjects with a response, n (%) [2]	10 (47.6)	6 (46.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.939
95% CI for the RR		(0.463, 1.906)
p-value for RR		0.8620
Day 8		
Number of subjects with a response, n (%) [2]	11 (52.4)	10 (76.9)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.423
95% CI for the RR		(0.875, 2.313)
p-value for RR		0.1547

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 15		
Number of subjects with a response, n (%) [2]	10 (47.6)	10 (76.9)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.565
95% CI for the RR		(0.924, 2.653)
p-value for RR		0.0960
Day 21		
Number of subjects with a response, n (%) [2]	14 (66.7)	10 (76.9)
Number of subjects with missing evaluation, n (%)	2 (9.5)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.118
95% CI for the RR		(0.744, 1.680)
p-value for RR		0.5911

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 45		
Number of subjects with a response, n (%) [2]	10 (47.6)	12 (92.3)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.878
95% CI for the RR		(1.162, 3.036)
p-value for RR		0.0101

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 3		
Number of subjects with a response, n (%) [2]	5 (25.0)	15 (71.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		3.025
95% CI for the RR		(1.423, 6.431)
p-value for RR		0.0040
Day 8		
Number of subjects with a response, n (%) [2]	10 (50.0)	17 (81.0)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.714
95% CI for the RR		(1.082, 2.716)
p-value for RR		0.0218

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	11 (55.0)	19 (90.5)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.741
95% CI for the RR		(1.151, 2.635)
p-value for RR		0.0087
Day 21		
Number of subjects with a response, n (%) [2]	11 (55.0)	17 (81.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.558
95% CI for the RR		(1.020, 2.381)
p-value for RR		0.0404

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 45		
Number of subjects with a response, n (%) [2]	15 (75.0)	18 (85.7)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.210
95% CI for the RR		(0.908, 1.612)
p-value for RR		0.1934

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 3		
Number of subjects with a response, n (%) [2]	20 (58.8)	19 (45.2)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.774
95% CI for the RR		(0.504, 1.190)
p-value for RR		0.2433
Day 8		
Number of subjects with a response, n (%) [2]	27 (79.4)	32 (76.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.966
95% CI for the RR		(0.761, 1.226)
p-value for RR		0.7768

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 15		
Number of subjects with a response, n (%) [2]	27 (79.4)	30 (71.4)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.906
95% CI for the RR		(0.701, 1.170)
p-value for RR		0.4478
Day 21		
Number of subjects with a response, n (%) [2]	24 (70.6)	30 (71.4)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.019
95% CI for the RR		(0.765, 1.356)
p-value for RR		0.8980

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 45		
Number of subjects with a response, n (%) [2]	25 (73.5)	32 (76.2)
Number of subjects with missing evaluation, n (%)	3 (8.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.043
95% CI for the RR		(0.809, 1.346)
p-value for RR		0.7441

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.5.2.1 .2 .2 .6 Beginn der PPD

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 3		
Number of subjects with a response, n (%) [2]	17 (53.1)	22 (68.8)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.301
95% CI for the RR		(0.893, 1.894)
p-value for RR		0.1702
Day 8		
Number of subjects with a response, n (%) [2]	21 (65.6)	26 (81.3)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.244
95% CI for the RR		(0.917, 1.689)
p-value for RR		0.1602

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 15		
Number of subjects with a response, n (%) [2]	20 (62.5)	26 (81.3)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.307
95% CI for the RR		(0.945, 1.806)
p-value for RR		0.1053
Day 21		
Number of subjects with a response, n (%) [2]	20 (62.5)	23 (71.9)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.156
95% CI for the RR		(0.825, 1.619)
p-value for RR		0.3999

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 45		
Number of subjects with a response, n (%) [2]	22 (68.8)	27 (84.4)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.234
95% CI for the RR		(0.939, 1.620)
p-value for RR		0.1311

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 3		
Number of subjects with a response, n (%) [2]	18 (41.9)	18 (40.9)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.991
95% CI for the RR		(0.602, 1.629)
p-value for RR		0.9708
Day 8		
Number of subjects with a response, n (%) [2]	27 (62.8)	33 (75.0)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.211
95% CI for the RR		(0.910, 1.611)
p-value for RR		0.1885

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	28 (65.1)	33 (75.0)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.168
95% CI for the RR		(0.886, 1.539)
p-value for RR		0.2714
Day 21		
Number of subjects with a response, n (%) [2]	29 (67.4)	34 (77.3)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.162
95% CI for the RR		(0.891, 1.514)
p-value for RR		0.2673

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	28 (65.1)	35 (79.5)
Number of subjects with missing evaluation, n (%)	3 (7.0)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.238
95% CI for the RR		(0.950, 1.615)
p-value for RR		0.1145

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.5.2.1 .2 .2 .7 PPD in der Familie

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 3		
Number of subjects with a response, n (%) [2]	4 (40.0)	4 (40.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.354
95% CI for the RR		(0.012, 10.568)
p-value for RR		0.5492
Day 8		
Number of subjects with a response, n (%) [2]	7 (70.0)	10 (100)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.506
95% CI for the RR		(0.027, 9.634)
p-value for RR		0.6505

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	7 (70.0)	9 (90.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.455
95% CI for the RR		(0.025, 8.297)
p-value for RR		0.5954
Day 21		
Number of subjects with a response, n (%) [2]	4 (40.0)	10 (100)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.886
95% CI for the RR		(0.023, 33.873)
p-value for RR		0.9479

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	7 (70.0)	9 (90.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.455
95% CI for the RR		(0.022, 9.569)
p-value for RR		0.6127

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 3		
Number of subjects with a response, n (%) [2]	31 (47.7)	36 (54.5)
Number of subjects with missing evaluation, n (%)	1 (1.5)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.176
95% CI for the RR		(0.849, 1.627)
p-value for RR		0.3291
Day 8		
Number of subjects with a response, n (%) [2]	41 (63.1)	49 (74.2)
Number of subjects with missing evaluation, n (%)	1 (1.5)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.210
95% CI for the RR		(0.963, 1.520)
p-value for RR		0.1022

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	41 (63.1)	50 (75.8)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.235
95% CI for the RR		(0.982, 1.553)
p-value for RR		0.0717
Day 21		
Number of subjects with a response, n (%) [2]	45 (69.2)	47 (71.2)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.057
95% CI for the RR		(0.848, 1.318)
p-value for RR		0.6204

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	43 (66.2)	53 (80.3)
Number of subjects with missing evaluation, n (%)	5 (7.7)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.248
95% CI for the RR		(1.015, 1.533)
p-value for RR		0.0353

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.5.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 3		
Number of subjects with a response, n (%) [2]	29 (49.2)	34 (51.5)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.070
95% CI for the RR		(0.764, 1.498)
p-value for RR		0.6944
Day 8		
Number of subjects with a response, n (%) [2]	39 (66.1)	50 (75.8)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.170
95% CI for the RR		(0.938, 1.460)
p-value for RR		0.1649

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	41 (69.5)	52 (78.8)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.157
95% CI for the RR		(0.940, 1.425)
p-value for RR		0.1683
Day 21		
Number of subjects with a response, n (%) [2]	39 (66.1)	49 (74.2)
Number of subjects with missing evaluation, n (%)	1 (1.7)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.147
95% CI for the RR		(0.913, 1.440)
p-value for RR		0.2401

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	41 (69.5)	54 (81.8)
Number of subjects with missing evaluation, n (%)	4 (6.8)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.202
95% CI for the RR		(0.986, 1.464)
p-value for RR		0.0682

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 3		
Number of subjects with a response, n (%) [2]	6 (37.5)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.503
95% CI for the RR		(0.634, 3.561)
p-value for RR		0.3550
Day 8		
Number of subjects with a response, n (%) [2]	9 (56.3)	9 (90.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.503
95% CI for the RR		(0.878, 2.572)
p-value for RR		0.1374

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	7 (43.8)	7 (70.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.503
95% CI for the RR		(0.718, 3.145)
p-value for RR		0.2799
Day 21		
Number of subjects with a response, n (%) [2]	10 (62.5)	8 (80.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.202
95% CI for the RR		(0.690, 2.095)
p-value for RR		0.5160

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	9 (56.3)	8 (80.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.336
95% CI for the RR		(0.740, 2.412)
p-value for RR		0.3371

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response (8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline). Missing total score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

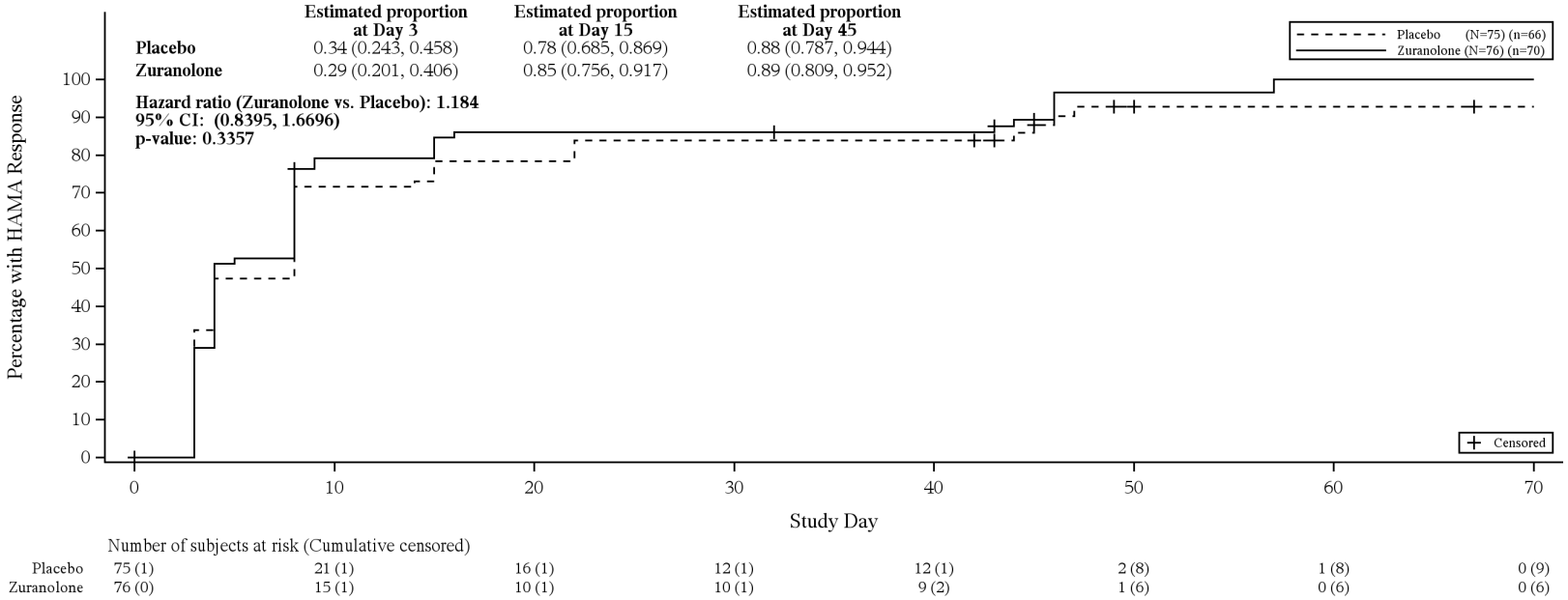
Source: biib125/v_a/germany_amnog/t-hama-resp15-201-by.sas:t-hama-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.5.2.2 TTE-Analysen

4.5.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-201-ovr.sas:f-hama-resp15-tte-201-ovr-itta.rtf **Run Date:** 15DEC2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	66 (88.0)	70 (92.1)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (4.0 , 8.0)	4.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 44.0)	8.0 (8.0 , 15.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.184
95% CI for the HR		(0.8395 , 1.6696)
p-value for the HR		0.3357

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-ovr.sas:t-hama-resp15-tte-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.5.2.2 .2 Subgruppen

4.5.2.2 .2 .1 Interaktionstest

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	66 (88.0)	70 (92.1)	
Age Group (years)			
18 - 24, n / N (%)	22/25 (88.0)	16/17 (94.1)	0.2622
25 - 45, n / N (%)	44/50 (88.0)	54/59 (91.5)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	22/22 (100.0)	27/30 (90.0)	0.0686
>=28, n / N (%)	44/53 (83.0)	43/46 (93.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	27/32 (84.4)	28/31 (90.3)	0.4431
White, n / N (%)	36/40 (90.0)	41/44 (93.2)	
Antidepressant Use at Baseline			
Yes, n / N (%)	11/13 (84.6)	15/16 (93.8)	0.9357
No, n / N (%)	55/62 (88.7)	55/60 (91.7)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-int.sas:t-hama-resp15-tte-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	17/21 (81.0)	13/13 (100.0)	0.1216(a)
25-29.9, n / N (%)	16/20 (80.0)	20/21 (95.2)	0.1940(b)
>=30, n / N (%)	33/34 (97.1)	37/42 (88.1)	0.0014(c)
Onset of PPD			
3rd Trimester, n / N (%)	28/32 (87.5)	31/32 (96.9)	0.8294
Postpartum, n / N (%)	38/43 (88.4)	39/44 (88.6)	
Family History of PPD			
Yes, n / N (%)	10/10 (100.0)	10/10 (100.0)	0.7766
No/Unknown, n / N (%)	56/65 (86.2)	60/66 (90.9)	
History of PPD			
1st Episode, n / N (%)	54/59 (91.5)	60/66 (90.9)	0.4822
Recurrent Episode, n / N (%)	12/16 (75.0)	10/10 (100.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	7/8 (87.5)	8/10 (80.0)	NA
>=20, n / N (%)	59/67 (88.1)	62/66 (93.9)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-int.sas:t-hama-resp15-tte-201-int-itta.rtf **Run Date:** 29JUL2025

4.5.2.2 .2 .2 Subgruppenanalysen

4.5.2.2 .2 .2 .1 Alter

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	22 (88.0)	16 (94.1)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	4.0 (3.0 , 15.0)	4.0 (3.0 , 5.0)
75th percentile - Q3 (95% CI)	22.0 (8.0, NE)	5.0 (4.0 , 8.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.459
95% CI for the HR		(0.7370 , 2.8894)
p-value for the HR		0.2781

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	44 (88.0)	54 (91.5)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (4.0 , 8.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	8.0 (8.0 , 45.0)	15.0 (8.0 , 43.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.041
95% CI for the HR		(0.6858 , 1.5810)
p-value for the HR		0.8496

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.5.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	22 (100.0)	27 (90.0)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (3.0 , 8.0)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	8.0 (8.0 , 22.0)	43.0 (8.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.755
95% CI for the HR		(0.4251 , 1.3405)
p-value for the HR		0.3371

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	44 (83.0)	43 (93.5)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (4.0 , 8.0)	4.0 (3.0 , 8.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 46.0)	8.0 (8.0 , 9.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.428
95% CI for the HR		(0.9244 , 2.2056)
p-value for the HR		0.1083

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.5.2.2 .2 .2 .3 Abstammung

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	27 (84.4)	28 (90.3)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	4.0 (3.0 , 8.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	15.0 (8.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.932
95% CI for the HR		(0.5333 , 1.6270)
p-value for the HR		0.8031

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	36 (90.0)	41 (93.2)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 46.0)	8.0 (8.0 , 16.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.302
95% CI for the HR		(0.8202 , 2.0661)
p-value for the HR		0.2631

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.5.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	11 (84.6)	15 (93.8)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 8.0)	3.5 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (3.0 , 8.0)	8.0 (3.0 , 8.0)
75th percentile - Q3 (95% CI)	8.0 (4.0, NE)	8.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.143
95% CI for the HR		(0.5206 , 2.5112)
p-value for the HR		0.7386

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	55 (88.7)	55 (91.7)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (4.0 , 8.0)	4.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 44.0)	8.5 (8.0 , 43.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.205
95% CI for the HR		(0.8220 , 1.7656)
p-value for the HR		0.3397

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.5.2.2 .2 .2 .5 BMI

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	17 (81.0)	13 (100.0)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.5 (3.0 , 4.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	6.0 (3.0 , 22.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	22.0 (8.0, NE)	8.0 (4.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.185
95% CI for the HR		(0.5677 , 2.4738)
p-value for the HR		0.6512

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	16 (80.0)	20 (95.2)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	5.5 (3.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (3.0 , 45.0)	4.0 (3.0 , 5.0)
75th percentile - Q3 (95% CI)	45.0 (8.0, NE)	8.0 (4.0 , 15.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.581
95% CI for the HR		(1.0923 , 6.0963)
p-value for the HR		0.0307

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	33 (97.1)	37 (88.1)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (NE, NE)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	4.0 (3.0 , 8.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	8.0 (4.0 , 15.0)	9.0 (8.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.743
95% CI for the HR		(0.4613 , 1.1961)
p-value for the HR		0.2212

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.5.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	28 (87.5)	31 (96.9)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (NE, NE)	3.0 (NE, NE)
50th percentile - median (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 5.0)
75th percentile - Q3 (95% CI)	8.0 (8.0, NE)	8.0 (4.0 , 15.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.195
95% CI for the HR		(0.7097 , 2.0114)
p-value for the HR		0.5032

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	38 (88.4)	39 (88.6)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (4.0 , 8.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 47.0)	8.5 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.146
95% CI for the HR		(0.7203 , 1.8236)
p-value for the HR		0.5651

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.5.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	10 (100.0)	10 (100.0)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 8.0)	4.0 (3.0, NE)
50th percentile - median (95% CI)	8.0 (3.0 , 8.0)	8.0 (3.0, NE)
75th percentile - Q3 (95% CI)	8.0 (8.0, NE)	8.0 (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.296
95% CI for the HR		(0.4841 , 3.4697)
p-value for the HR		0.6058

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	56 (86.2)	60 (90.9)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (4.0 , 8.0)	4.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 44.0)	9.0 (8.0 , 43.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.200
95% CI for the HR		(0.8247 , 1.7461)
p-value for the HR		0.3406

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.5.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	54 (91.5)	60 (90.9)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (NE, NE)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (3.0 , 8.0)	4.5 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 22.0)	9.0 (8.0 , 16.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.121
95% CI for the HR		(0.7679 , 1.6367)
p-value for the HR		0.5539

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	12 (75.0)	10 (100.0)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (4.0 , 15.0)	4.0 (3.0 , 8.0)
75th percentile - Q3 (95% CI)	47.0 (8.0, NE)	8.0 (4.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.478
95% CI for the HR		(0.5892 , 3.7057)
p-value for the HR		0.4053

NOTE 1: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing HAM-A total score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a HAM-A response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline HAM-A total score, and treatment.

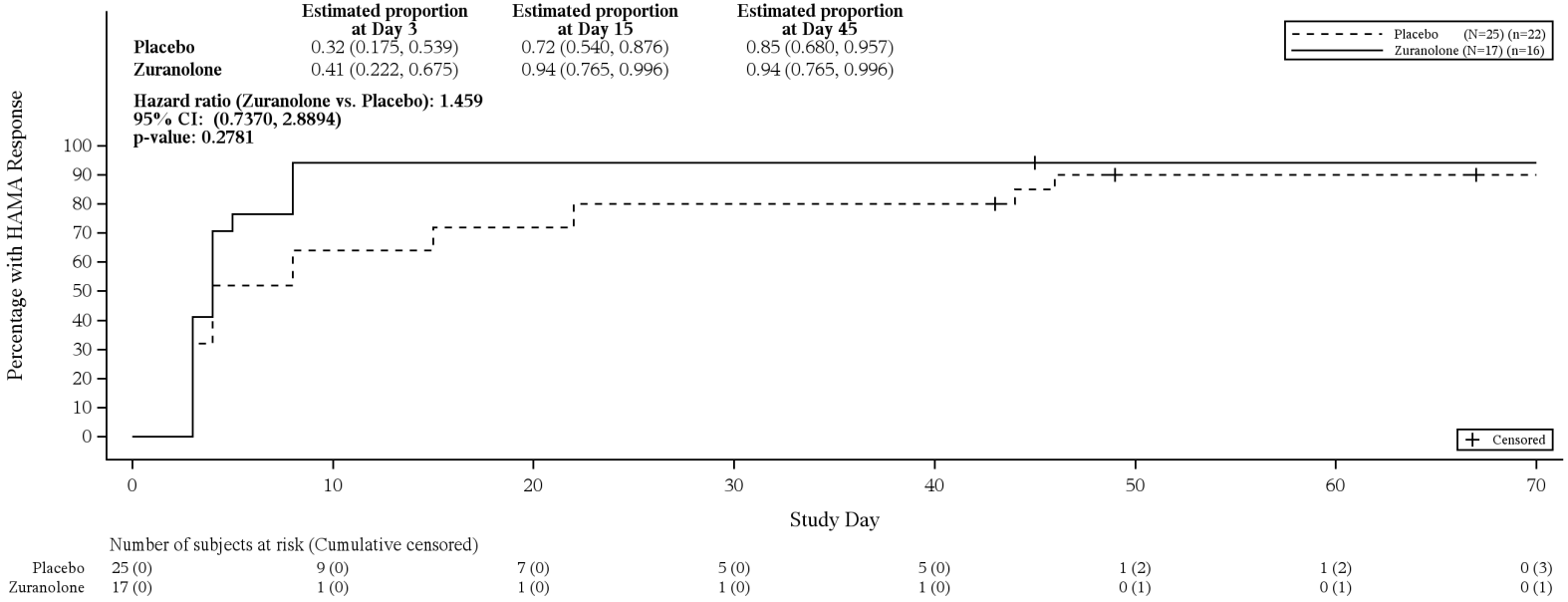
Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-201-by.sas:t-hama-resp15-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.5.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

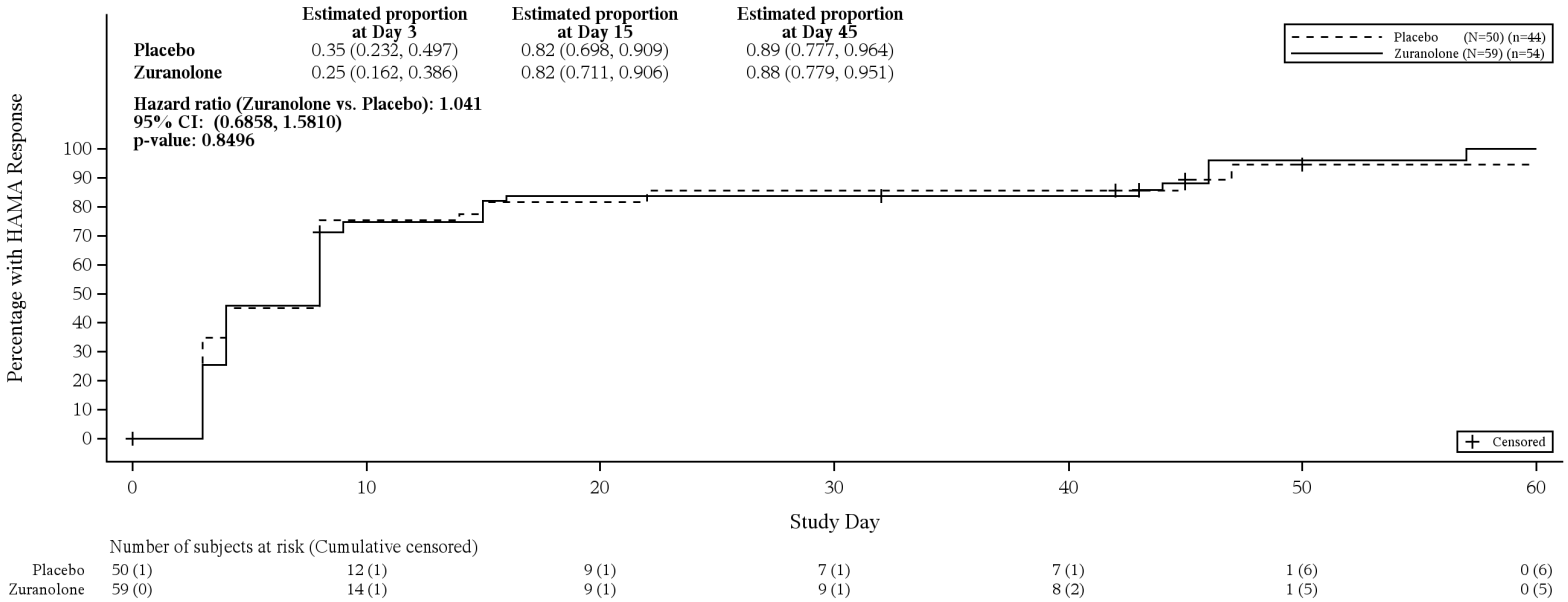
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-201-by.sas:f-hama-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 25-45



Number of subjects at risk (Cumulative censored)

Placebo	50 (1)	12 (1)	9 (1)	7 (1)	7 (1)	1 (6)	0 (6)
Zuranolone	59 (0)	14 (1)	9 (1)	9 (1)	8 (2)	1 (5)	0 (5)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

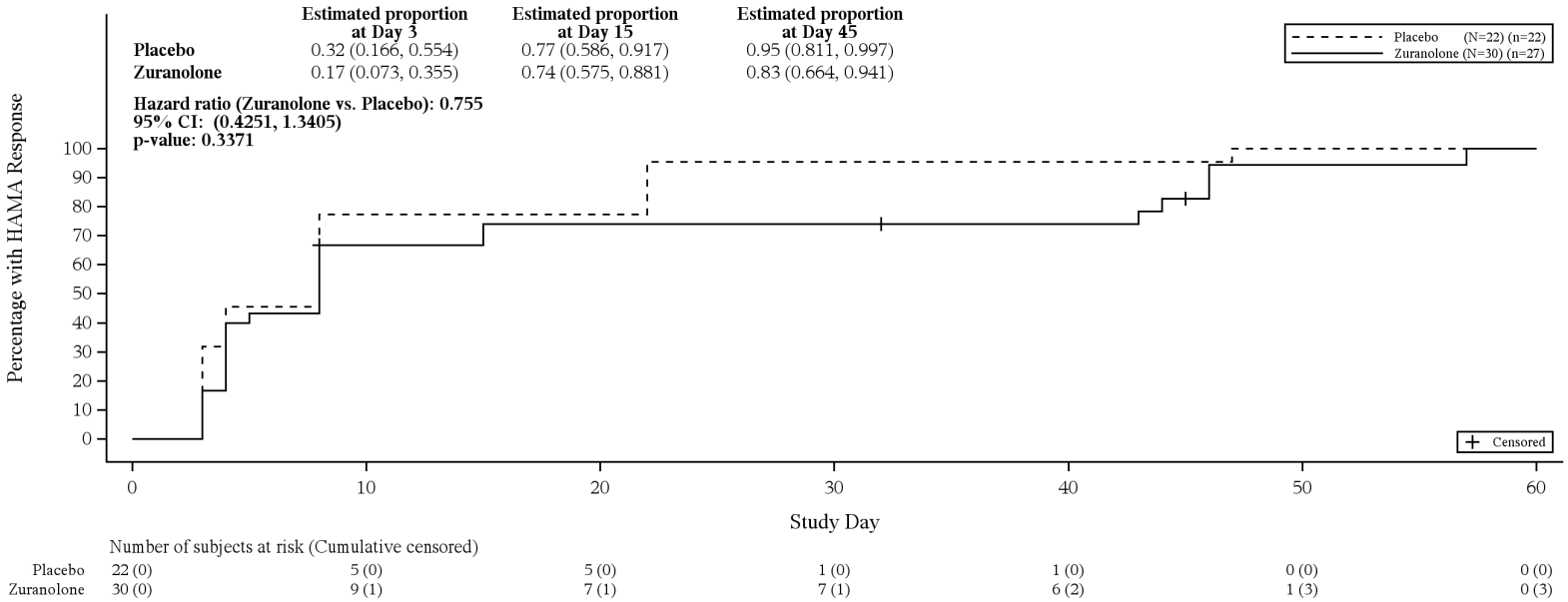
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-201-by.sas:f-hama-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 3 of 17

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	5 (0)	5 (0)	1 (0)	1 (0)	0 (0)	0 (0)
Zuranolone	30 (0)	9 (1)	7 (1)	7 (1)	6 (2)	1 (3)	0 (3)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

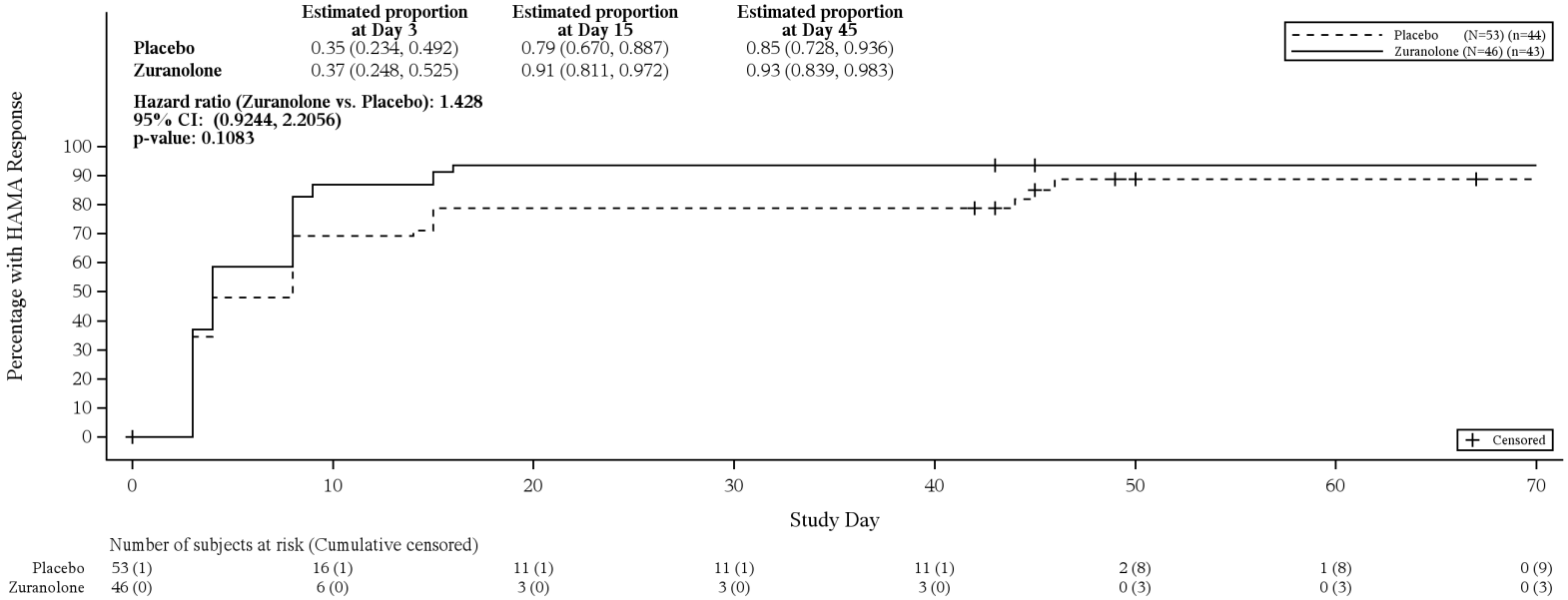
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 4 of 17

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

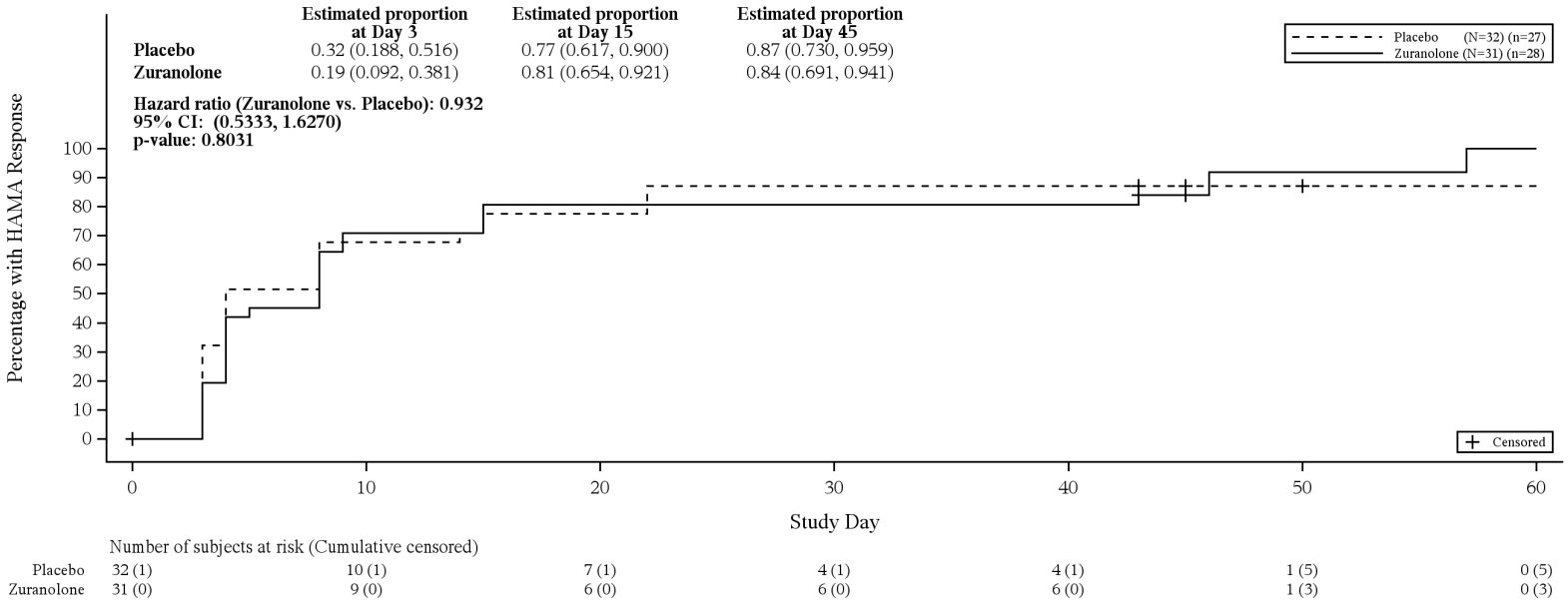
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Number of subjects at risk (Cumulative censored)

Placebo	32 (1)	10 (1)	7 (1)	4 (1)	4 (1)	1 (5)	0 (5)
Zuranolone	31 (0)	9 (0)	6 (0)	6 (0)	6 (0)	1 (3)	0 (3)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

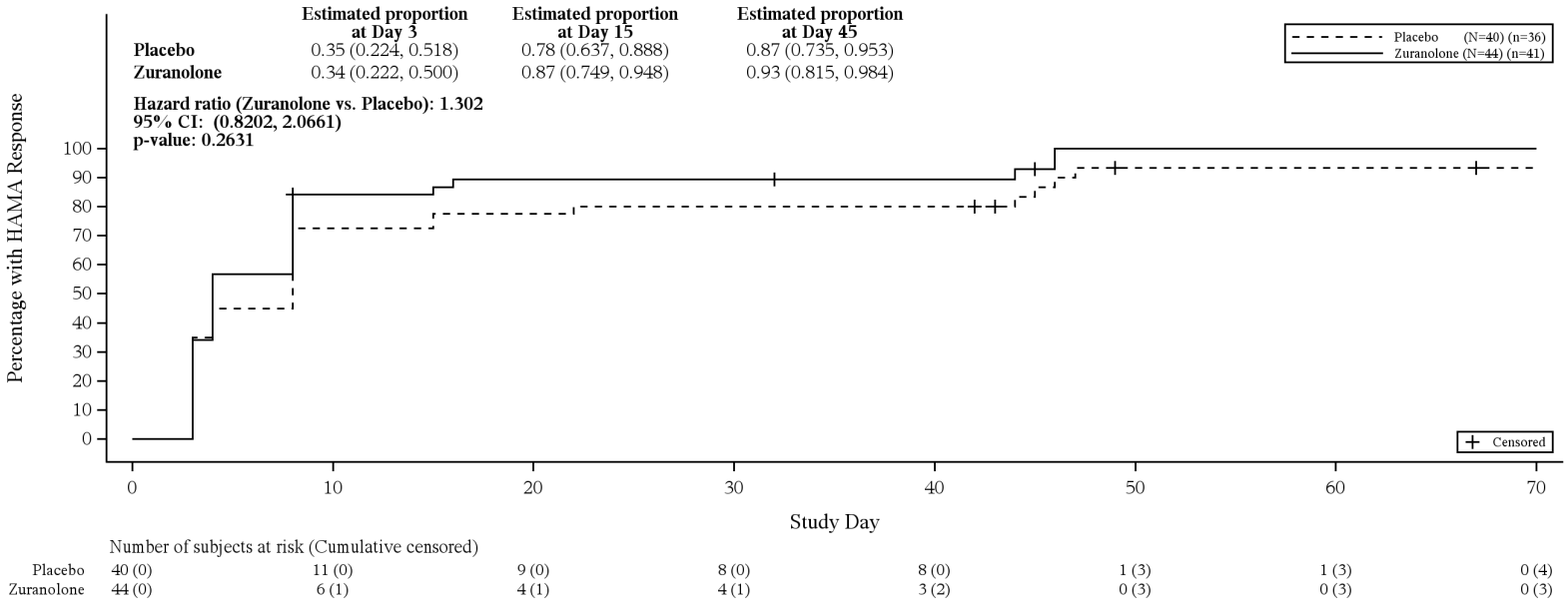
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

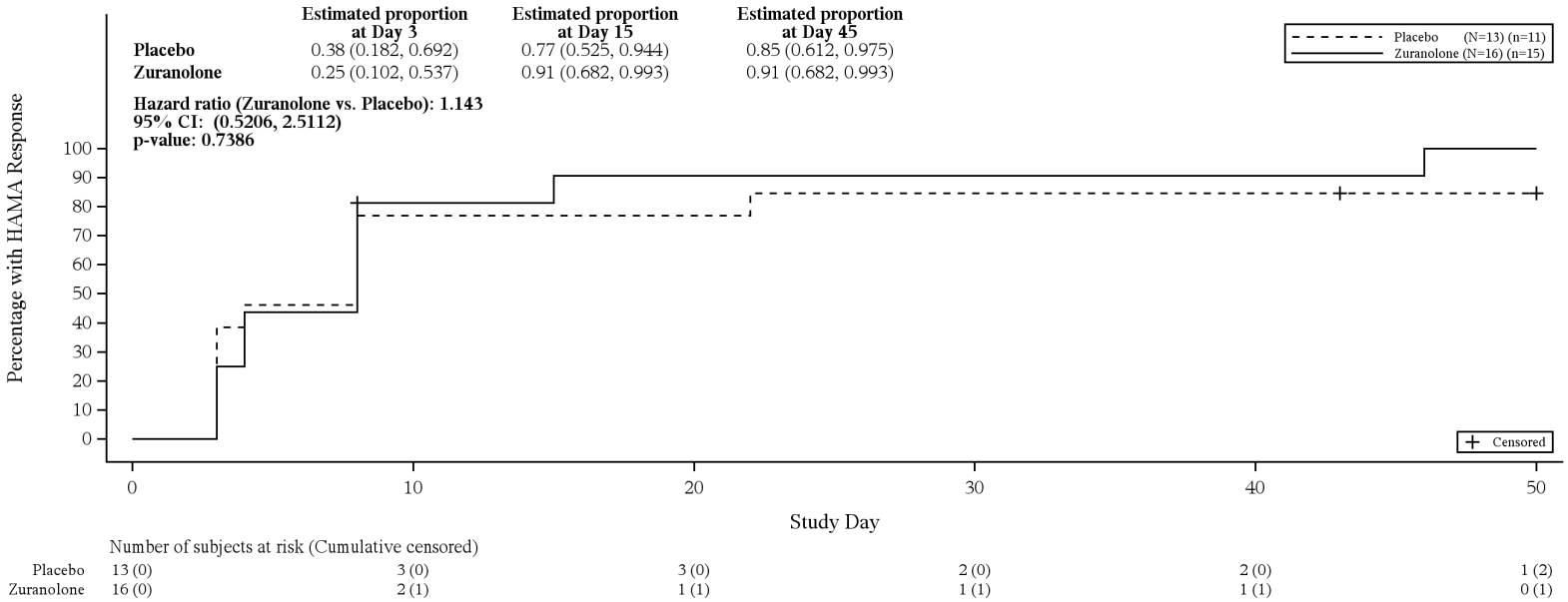
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-201-by.sas:f-hama-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

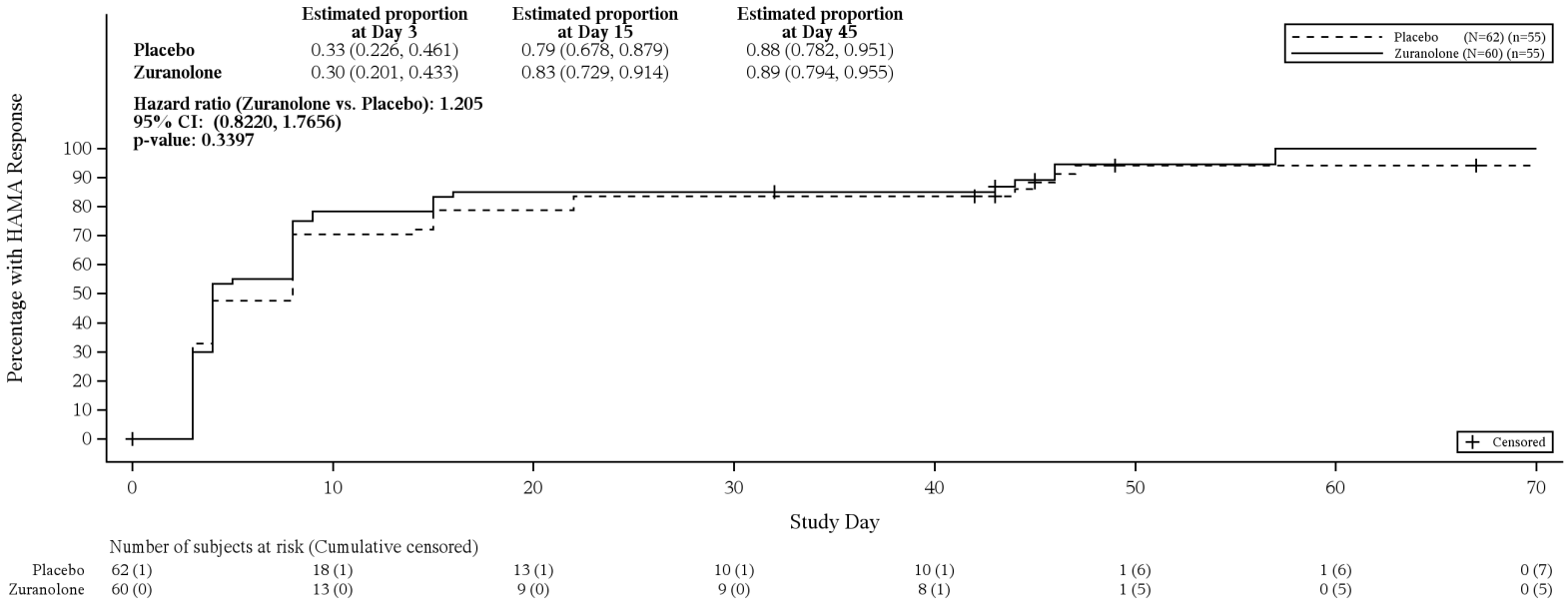
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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 8 of 17

Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

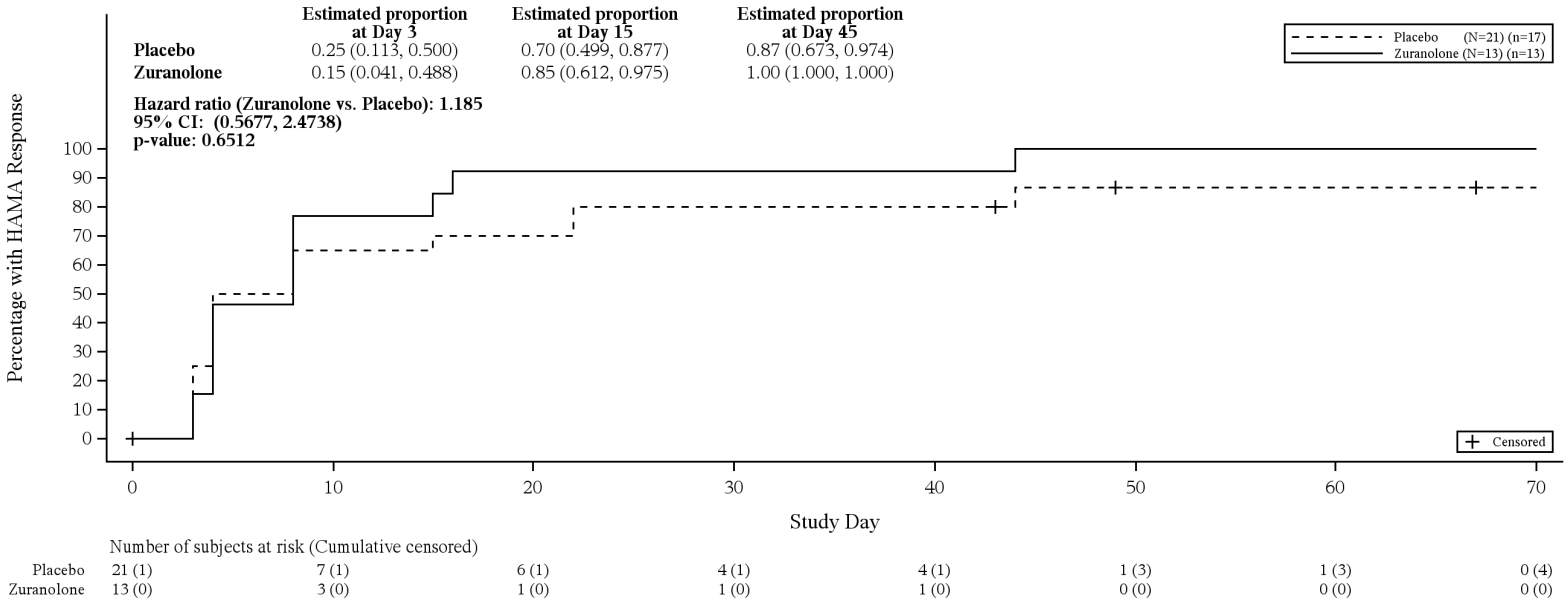
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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

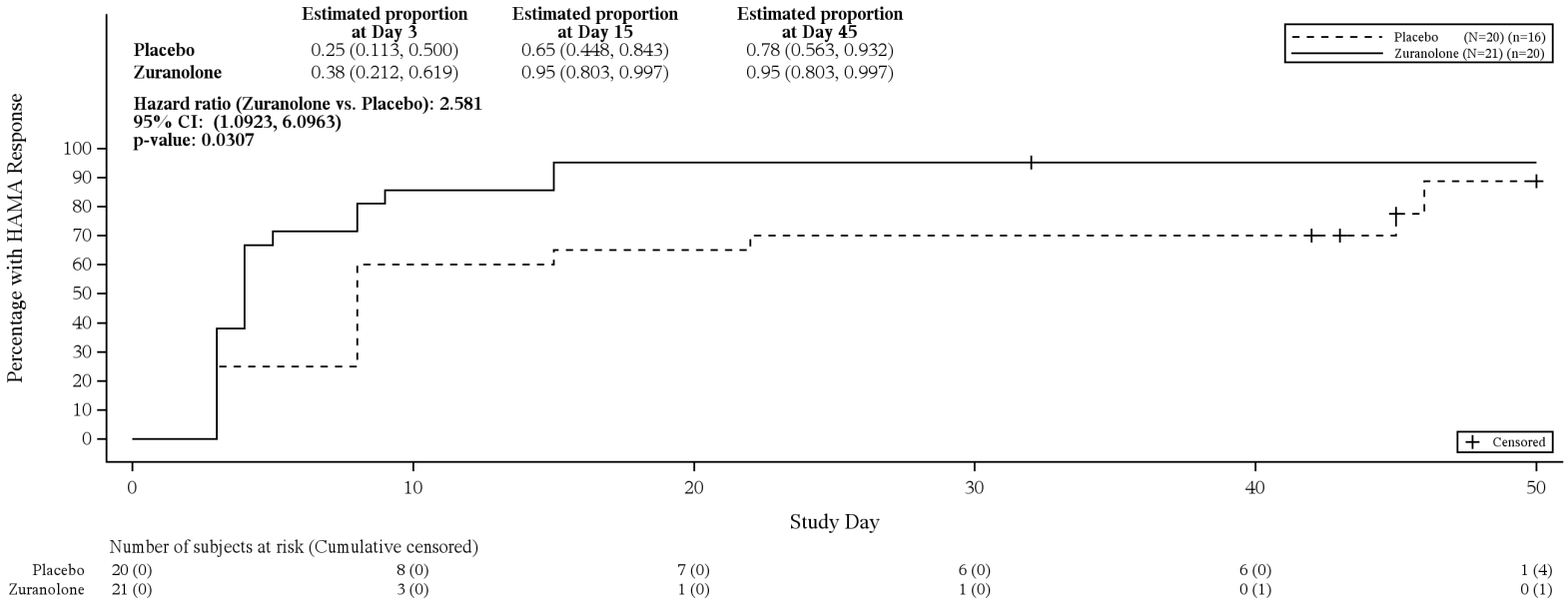
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Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-201-by.sas:f-hama-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

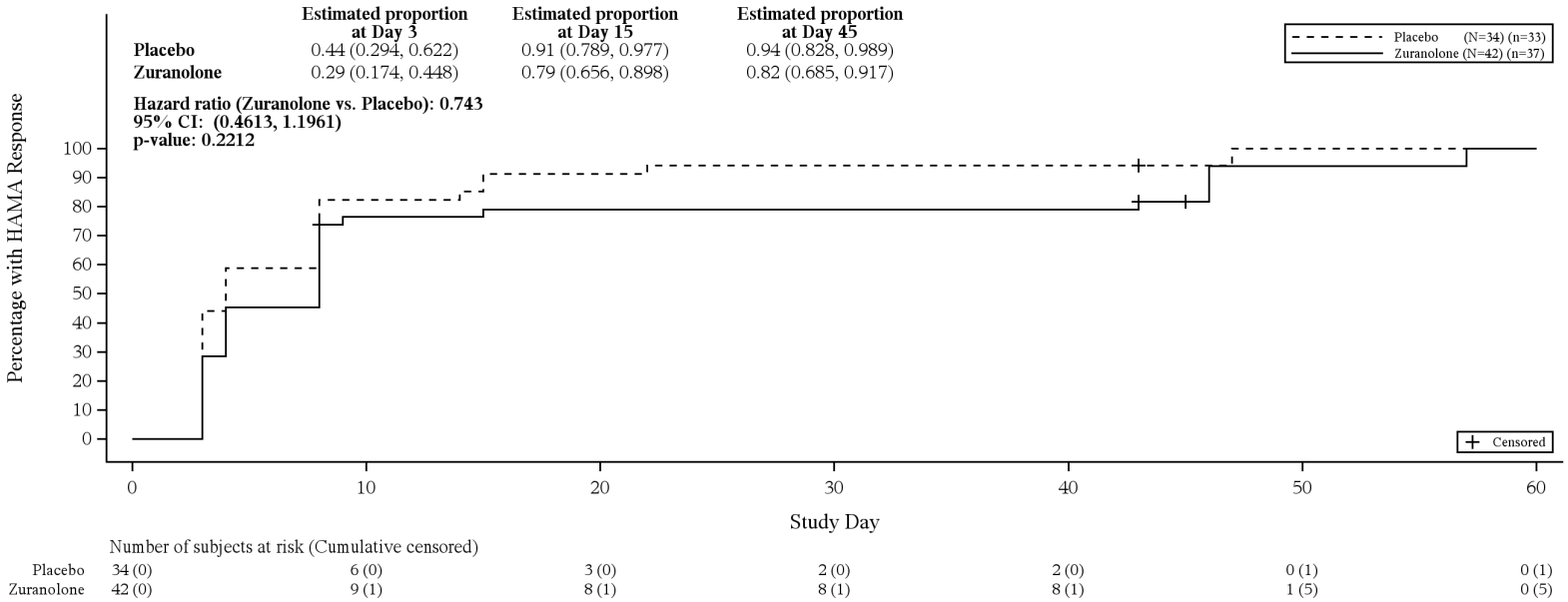
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Number of subjects at risk (Cumulative censored)

Placebo	34 (0)	6 (0)	3 (0)	2 (0)	2 (0)	0 (1)	0 (1)
Zuranolone	42 (0)	9 (1)	8 (1)	8 (1)	8 (1)	1 (5)	0 (5)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

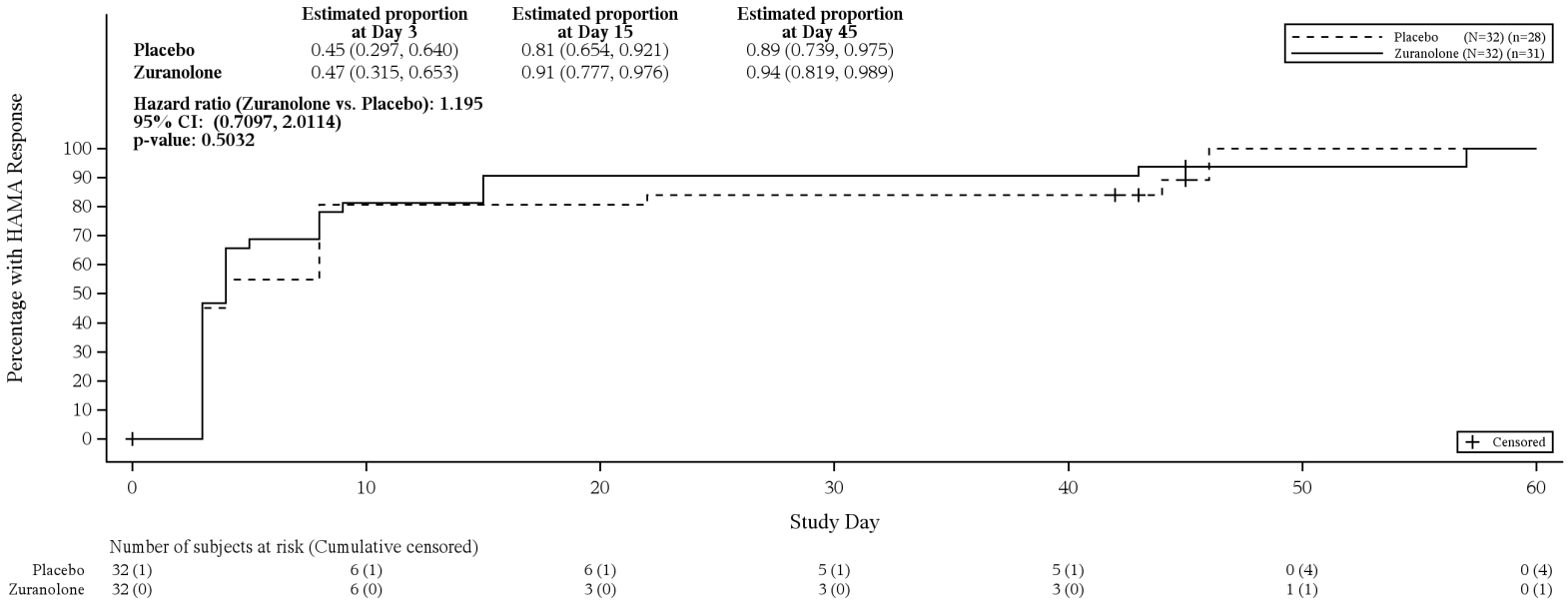
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

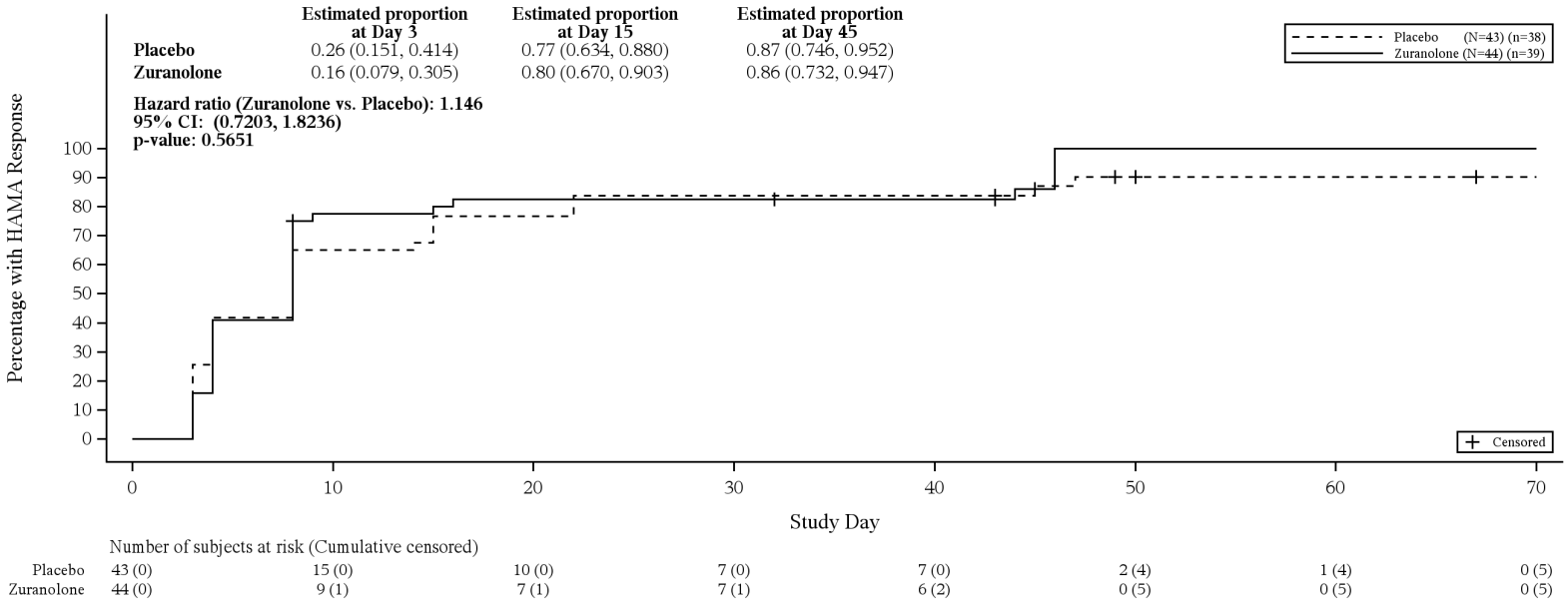
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-201-by.sas:f-hama-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Number of subjects at risk (Cumulative censored)

Placebo	43 (0)	15 (0)	10 (0)	7 (0)	7 (0)	2 (4)	1 (4)	0 (5)
Zuranolone	44 (0)	9 (1)	7 (1)	7 (1)	6 (2)	0 (5)	0 (5)	0 (5)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

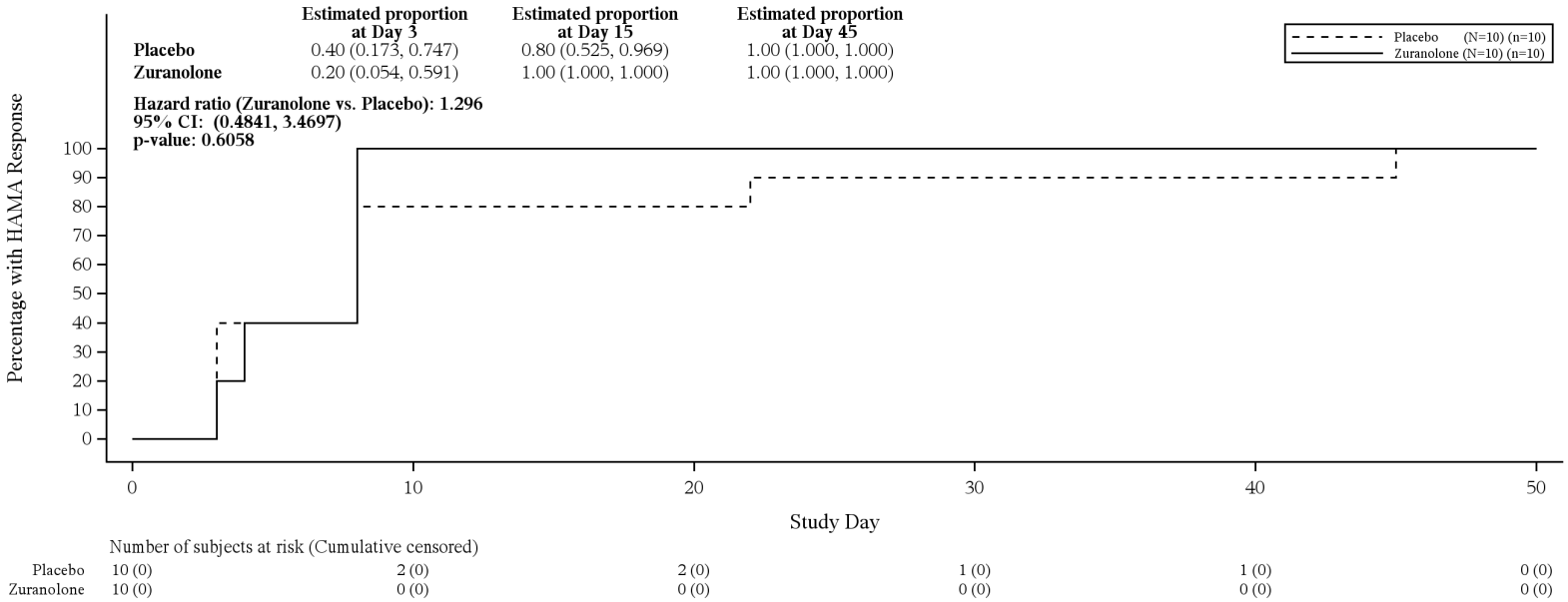
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-201-by.sas:f-hama-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 14 of 17

Family History of PPD = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

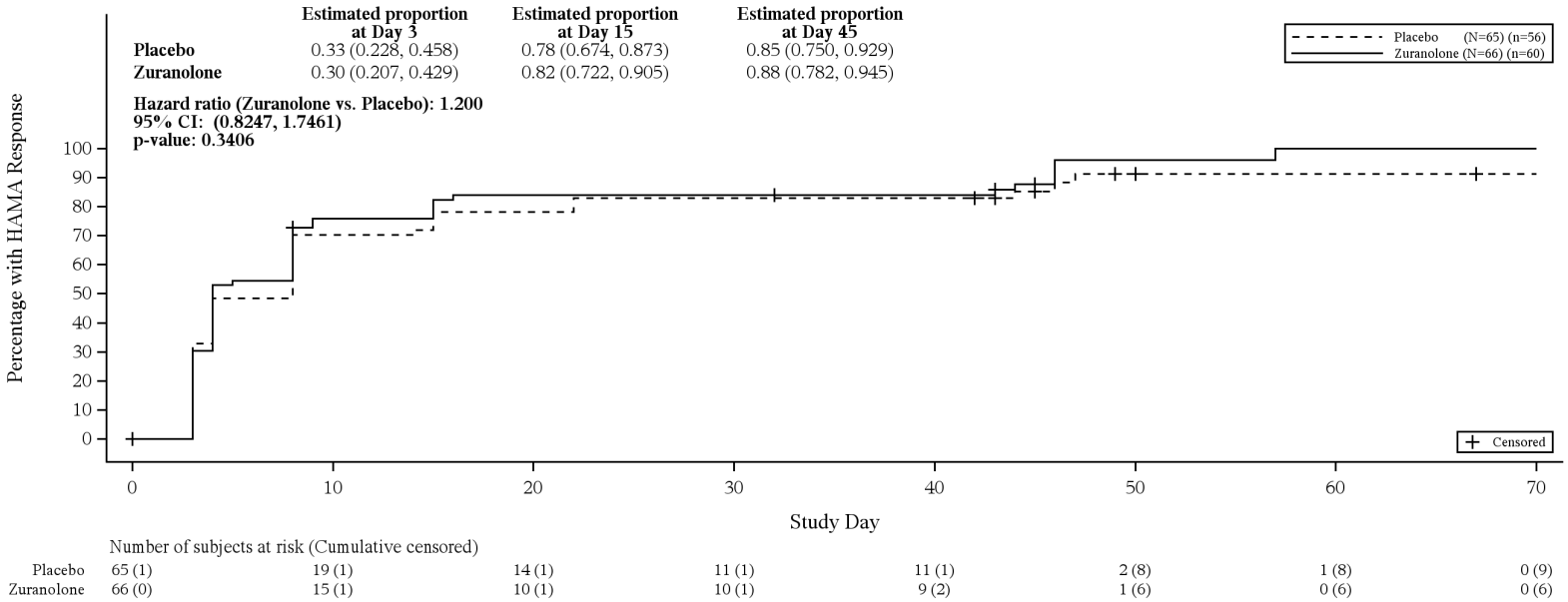
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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

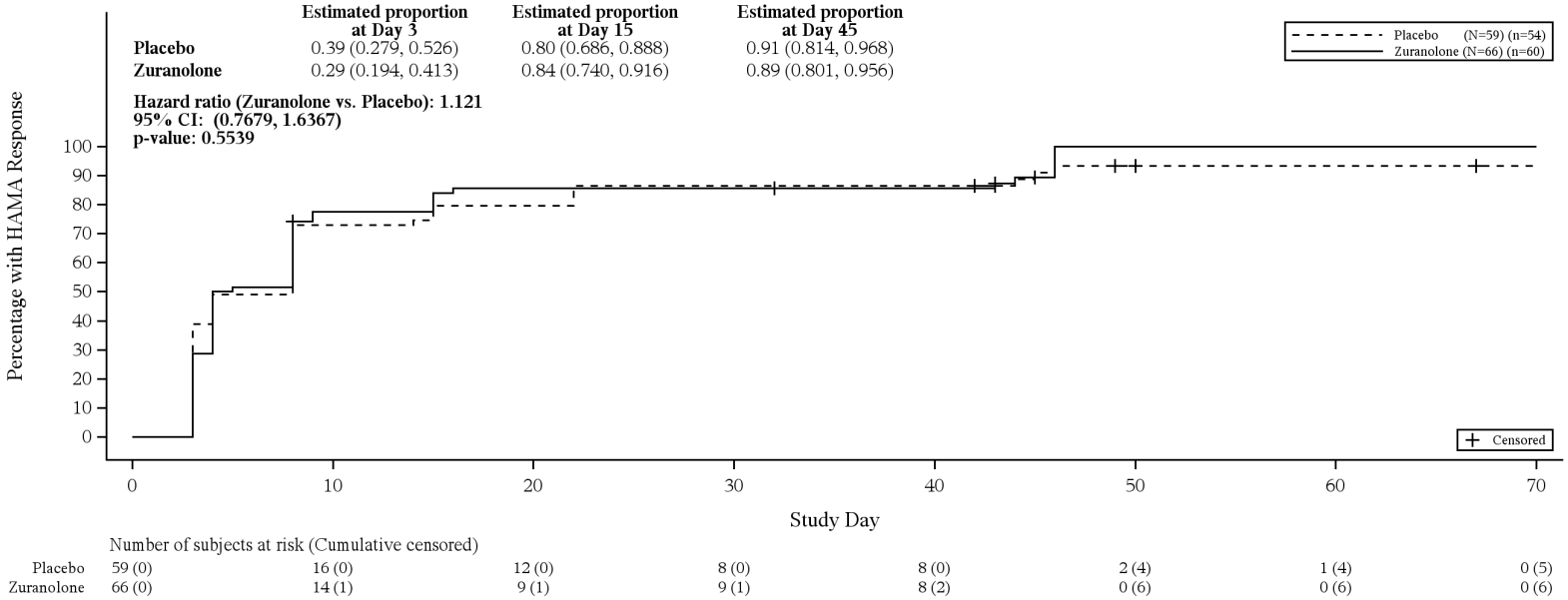
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

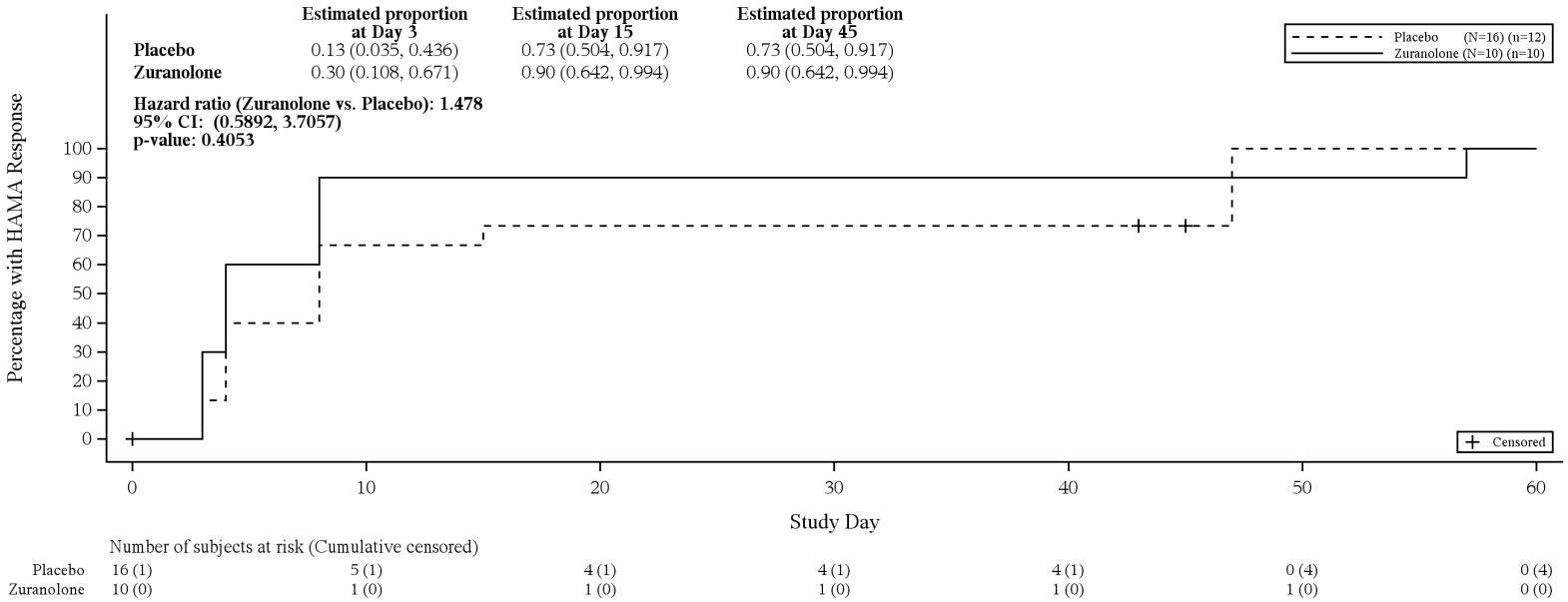
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Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-201-by.sas:f-hama-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 17 of 17

History of PPD = Recurrent Episode



Number of subjects at risk (Cumulative censored)

Placebo	16 (1)	5 (1)	4 (1)	4 (1)	4 (1)	0 (4)	0 (4)
Zuranolone	10 (0)	1 (0)	1 (0)	1 (0)	1 (0)	1 (0)	0 (0)

Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing HAM-A total score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: HAM-A response is defined as 8.4 points (15% of HAM-A total scale range 0-56) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

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4.6 CGI-S

4.6.1 MMRM

Model-based Results on Change from Baseline in Clinical Global Impression - Severity (CGI-S): 217-PPD-201B - ITT population

Page: 1 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 3		
n	74	74
LS Mean (SE)	-0.91 (0.127)	-1.22 (0.127)
95% CI for the LS Mean	-1.16, -0.65	-1.47, -0.97
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.32 (0.180)
95% CI for the LS Mean		-0.67, 0.04
p-value		0.0808
Hedges' g (Zuranolone vs. Placebo)		-0.288
95% CI for Hedges' g		-0.6115, 0.0363
Day 8		
n	74	75
LS Mean (SE)	-1.43 (0.148)	-2.05 (0.146)
95% CI for the LS Mean	-1.73, -1.14	-2.34, -1.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.62 (0.208)
95% CI for the LS Mean		-1.03, -0.21
p-value		0.0035
Hedges' g (Zuranolone vs. Placebo)		-0.484
95% CI for Hedges' g		-0.8098, -0.1582

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: CGI-S uses a 7-point scale; a lower score indicates better outcome.
Source: biib125/v_a/germany_amnog/t-cgis-mmrm-201-ovr.sas:t-cgis-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Clinical Global Impression - Severity (CGI-S): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	-1.70 (0.155)	-2.39 (0.154)
95% CI for the LS Mean	-2.01, -1.40	-2.70, -2.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.69 (0.219)
95% CI for the LS Mean		-1.12, -0.26
p-value		0.0020
Hedges' g (Zuranolone vs. Placebo)		-0.518
95% CI for Hedges' g		-0.8462, -0.1888
Day 21		
n	73	74
LS Mean (SE)	-1.85 (0.160)	-2.47 (0.159)
95% CI for the LS Mean	-2.17, -1.53	-2.78, -2.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.62 (0.226)
95% CI for the LS Mean		-1.07, -0.17
p-value		0.0069
Hedges' g (Zuranolone vs. Placebo)		-0.450
95% CI for Hedges' g		-0.7778, -0.1230

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: CGI-S uses a 7-point scale; a lower score indicates better outcome.
Source: biib125/v_a/germany_amnog/t-cgis-mmrm-201-ovr.sas:t-cgis-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Clinical Global Impression - Severity (CGI-S): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 45		
n	68	73
LS Mean (SE)	-2.01 (0.146)	-2.75 (0.143)
95% CI for the LS Mean	-2.30, -1.72	-3.03, -2.47
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.75 (0.205)
95% CI for the LS Mean		-1.15, -0.34
p-value		0.0004
Hedges' g (Zuranolone vs. Placebo)		-0.611
95% CI for Hedges' g		-0.9487, -0.2729

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure.
NOTE 2: CGI-S uses a 7-point scale; a lower score indicates better outcome.
Source: biib125/v_a/germany_amnog/t-cgis-mmrm-201-ovr.sas:t-cgis-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.6.2 Ansprechen

4.6.2.1 Responder-Analysen

4.6.2.1 .1 ITT-Population

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	75	76
Day 3		
Number of subjects with a response, n (%) [2]	18 (24.0)	31 (40.8)
Number of subjects with missing evaluation, n (%)	1 (1.3)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.618
95% CI for the RR		(1.011, 2.588)
p-value for RR		0.0447
OR - Odds Ratio (Zuranolone vs. Placebo)		1.982
95% CI for the OR		(0.957, 4.103)
p-value for OR		0.0655
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-ovr.sas:t-cgis-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with a response, n (%) [2]	32 (42.7)	47 (61.8)
Number of subjects with missing evaluation, n (%)	1 (1.3)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.380
95% CI for the RR		(1.008, 1.889)
p-value for RR		0.0446
OR - Odds Ratio (Zuranolone vs. Placebo)		2.177
95% CI for the OR		(1.052, 4.507)
p-value for OR		0.0361
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-ovr.sas:t-cgis-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with a response, n (%) [2]	36 (48.0)	53 (69.7)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.383
95% CI for the RR		(1.052, 1.818)
p-value for RR		0.0202
OR - Odds Ratio (Zuranolone vs. Placebo)		2.600
95% CI for the OR		(1.230, 5.494)
p-value for OR		0.0123
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-ovr.sas:t-cgis-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with a response, n (%) [2]	38 (50.7)	52 (68.4)
Number of subjects with missing evaluation, n (%)	2 (2.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.285
95% CI for the RR		(0.994, 1.662)
p-value for RR		0.0555
OR - Odds Ratio (Zuranolone vs. Placebo)		2.145
95% CI for the OR		(1.054, 4.367)
p-value for OR		0.0353
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-ovr.sas:t-cgis-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	37 (49.3)	58 (76.3)
Number of subjects with missing evaluation, n (%)	7 (9.3)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.472
95% CI for the RR		(1.153, 1.881)
p-value for RR		0.0019
OR - Odds Ratio (Zuranolone vs. Placebo)		3.500
95% CI for the OR		(1.661, 7.373)
p-value for OR		0.0010
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NE
95% CI for the ARR		NE
p-value for ARR		NE

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively. Relative risk is based on Poisson distribution. NE indicates not estimable due to model not converging.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-ovr.sas:t-cgis-resp15-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.6.2.1 .2 Subgruppen

4.6.2.1 .2 .1 Interaktionstest

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response at Day 15, n (%)	36 (48.0)	53 (69.7)	
Number of subjects with response at Day 45, n (%)	37 (49.3)	58 (76.3)	
Age Group (years)			0.3462
Day 15			
18 - 24, n / N (%)	12/25 (48.0)	11/17 (64.7)	
25 - 45, n / N (%)	24/50 (48.0)	42/59 (71.2)	
Day 45			
18 - 24, n / N (%)	13/25 (52.0)	10/17 (58.8)	
25 - 45, n / N (%)	24/50 (48.0)	48/59 (81.4)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-int.sas:t-cgis-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.1498
Day 15			
<28, n / N (%)	11/22 (50.0)	18/30 (60.0)	
>=28, n / N (%)	25/53 (47.2)	35/46 (76.1)	
Day 45			
<28, n / N (%)	12/22 (54.5)	21/30 (70.0)	
>=28, n / N (%)	25/53 (47.2)	37/46 (80.4)	
Race Group (Black or African American, White)			0.0848
Day 15			
Black or African American, n / N (%)	18/32 (56.3)	20/31 (64.5)	
White, n / N (%)	17/40 (42.5)	32/44 (72.7)	
Day 45			
Black or African American, n / N (%)	19/32 (59.4)	22/31 (71.0)	
White, n / N (%)	17/40 (42.5)	35/44 (79.5)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-int.sas:t-cgis-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.3431
Day 15			
Yes, n / N (%)	5/13 (38.5)	12/16 (75.0)	
No, n / N (%)	31/62 (50.0)	41/60 (68.3)	
Day 45			
Yes, n / N (%)	3/13 (23.1)	11/16 (68.8)	
No, n / N (%)	34/62 (54.8)	47/60 (78.3)	
BMI (kg/m^2) Group			0.3942(a) 0.4328(b) 0.0812(c)
Day 15			
<=24.9, n / N (%)	11/21 (52.4)	8/13 (61.5)	
25-29.9, n / N (%)	8/20 (40.0)	17/21 (81.0)	
>=30, n / N (%)	17/34 (50.0)	28/42 (66.7)	
Day 45			
<=24.9, n / N (%)	9/21 (42.9)	9/13 (69.2)	
25-29.9, n / N (%)	11/20 (55.0)	18/21 (85.7)	
>=30, n / N (%)	17/34 (50.0)	31/42 (73.8)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-int.sas:t-cgis-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.6978
Day 15			
3rd Trimester, n / N (%)	15/32 (46.9)	23/32 (71.9)	
Postpartum, n / N (%)	21/43 (48.8)	30/44 (68.2)	
Day 45			
3rd Trimester, n / N (%)	20/32 (62.5)	26/32 (81.3)	
Postpartum, n / N (%)	17/43 (39.5)	32/44 (72.7)	
Family History of PPD			0.3706
Day 15			
Yes, n / N (%)	4/10 (40.0)	7/10 (70.0)	
No/Unknown, n / N (%)	32/65 (49.2)	46/66 (69.7)	
Day 45			
Yes, n / N (%)	6/10 (60.0)	7/10 (70.0)	
No/Unknown, n / N (%)	31/65 (47.7)	51/66 (77.3)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-int.sas:t-cgis-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.2421
Day 15			
1st Episode, n / N (%)	32/59 (54.2)	47/66 (71.2)	
Recurrent Episode, n / N (%)	4/16 (25.0)	6/10 (60.0)	
Day 45			
1st Episode, n / N (%)	31/59 (52.5)	52/66 (78.8)	
Recurrent Episode, n / N (%)	6/16 (37.5)	6/10 (60.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	5/8 (62.5)	8/10 (80.0)	
>=20, n / N (%)	31/67 (46.3)	45/66 (68.2)	
Day 45			
<20, n / N (%)	5/8 (62.5)	7/10 (70.0)	
>=20, n / N (%)	32/67 (47.8)	51/66 (77.3)	

NOTE 1: p-value is derived using Method 3, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-int.sas:t-cgis-resp15-201-int-itta.rtf **Run Date:** 30JUL2025

4.6.2.1 .2 .2 Subgruppenanalysen

4.6.2.1 .2 .2 .1 Alter

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 3		
Number of subjects with a response, n (%) [2]	7 (28.0)	9 (52.9)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.531
95% CI for the RR		(0.720, 3.256)
p-value for RR		0.2685
Day 8		
Number of subjects with a response, n (%) [2]	9 (36.0)	12 (70.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.588
95% CI for the RR		(0.863, 2.920)
p-value for RR		0.1371

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 15		
Number of subjects with a response, n (%) [2]	12 (48.0)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.092
95% CI for the RR		(0.652, 1.826)
p-value for RR		0.7386
Day 21		
Number of subjects with a response, n (%) [2]	12 (48.0)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.092
95% CI for the RR		(0.644, 1.850)
p-value for RR		0.7450

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

Page: 3 of 6

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 45		
Number of subjects with a response, n (%) [2]	13 (52.0)	10 (58.8)
Number of subjects with missing evaluation, n (%)	1 (4.0)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.916
95% CI for the RR		(0.576, 1.457)
p-value for RR		0.7109

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	50	59
Day 3		
Number of subjects with a response, n (%) [2]	11 (22.0)	22 (37.3)
Number of subjects with missing evaluation, n (%)	1 (2.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.679
95% CI for the RR		(0.917, 3.073)
p-value for RR		0.0932
Day 8		
Number of subjects with a response, n (%) [2]	23 (46.0)	35 (59.3)
Number of subjects with missing evaluation, n (%)	1 (2.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.277
95% CI for the RR		(0.884, 1.844)
p-value for RR		0.1921

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 15		
Number of subjects with a response, n (%) [2]	24 (48.0)	42 (71.2)
Number of subjects with missing evaluation, n (%)	2 (4.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.469
95% CI for the RR		(1.059, 2.038)
p-value for RR		0.0214
Day 21		
Number of subjects with a response, n (%) [2]	26 (52.0)	41 (69.5)
Number of subjects with missing evaluation, n (%)	2 (4.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.323
95% CI for the RR		(0.980, 1.786)
p-value for RR		0.0671

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 45		
Number of subjects with a response, n (%) [2]	24 (48.0)	48 (81.4)
Number of subjects with missing evaluation, n (%)	6 (12.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.679
95% CI for the RR		(1.245, 2.264)
p-value for RR		0.0007

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.6.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Page: 1 of 6

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 3		
Number of subjects with a response, n (%) [2]	6 (27.3)	9 (30.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.978
95% CI for the RR		(0.439, 2.178)
p-value for RR		0.9561
Day 8		
Number of subjects with a response, n (%) [2]	9 (40.9)	17 (56.7)
Number of subjects with missing evaluation, n (%)	0	1 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.231
95% CI for the RR		(0.717, 2.114)
p-value for RR		0.4504

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 15		
Number of subjects with a response, n (%) [2]	11 (50.0)	18 (60.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.067
95% CI for the RR		(0.682, 1.669)
p-value for RR		0.7776
Day 21		
Number of subjects with a response, n (%) [2]	11 (50.0)	16 (53.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.948
95% CI for the RR		(0.598, 1.503)
p-value for RR		0.8207

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 45		
Number of subjects with a response, n (%) [2]	12 (54.5)	21 (70.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.141
95% CI for the RR		(0.801, 1.624)
p-value for RR		0.4647

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	53	46
Day 3		
Number of subjects with a response, n (%) [2]	12 (22.6)	22 (47.8)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.050
95% CI for the RR		(1.154, 3.640)
p-value for RR		0.0143
Day 8		
Number of subjects with a response, n (%) [2]	23 (43.4)	30 (65.2)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.458
95% CI for the RR		(1.008, 2.110)
p-value for RR		0.0453

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 15		
Number of subjects with a response, n (%) [2]	25 (47.2)	35 (76.1)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.565
95% CI for the RR		(1.128, 2.172)
p-value for RR		0.0074
Day 21		
Number of subjects with a response, n (%) [2]	27 (50.9)	36 (78.3)
Number of subjects with missing evaluation, n (%)	2 (3.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.491
95% CI for the RR		(1.106, 2.010)
p-value for RR		0.0088

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 45		
Number of subjects with a response, n (%) [2]	25 (47.2)	37 (80.4)
Number of subjects with missing evaluation, n (%)	6 (11.3)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.655
95% CI for the RR		(1.216, 2.251)
p-value for RR		0.0013

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.6.2.1 .2 .2 .3 Abstammung

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	32	31
Day 3		
Number of subjects with a response, n (%) [2]	10 (31.3)	11 (35.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.165
95% CI for the RR		(0.614, 2.212)
p-value for RR		0.6399
Day 8		
Number of subjects with a response, n (%) [2]	16 (50.0)	20 (64.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.324
95% CI for the RR		(0.863, 2.031)
p-value for RR		0.1982

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 15		
Number of subjects with a response, n (%) [2]	18 (56.3)	20 (64.5)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.177
95% CI for the RR		(0.797, 1.739)
p-value for RR		0.4127
Day 21		
Number of subjects with a response, n (%) [2]	21 (65.6)	18 (58.1)
Number of subjects with missing evaluation, n (%)	1 (3.1)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.908
95% CI for the RR		(0.639, 1.291)
p-value for RR		0.5911

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 45		
Number of subjects with a response, n (%) [2]	19 (59.4)	22 (71.0)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.227
95% CI for the RR		(0.864, 1.742)
p-value for RR		0.2538

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 3		
Number of subjects with a response, n (%) [2]	8 (20.0)	19 (43.2)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.970
95% CI for the RR		(0.977, 3.972)
p-value for RR		0.0581
Day 8		
Number of subjects with a response, n (%) [2]	15 (37.5)	26 (59.1)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.438
95% CI for the RR		(0.904, 2.288)
p-value for RR		0.1255

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	17 (42.5)	32 (72.7)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.561
95% CI for the RR		(1.054, 2.312)
p-value for RR		0.0261
Day 21		
Number of subjects with a response, n (%) [2]	16 (40.0)	34 (77.3)
Number of subjects with missing evaluation, n (%)	1 (2.5)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.763
95% CI for the RR		(1.187, 2.618)
p-value for RR		0.0050

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	17 (42.5)	35 (79.5)
Number of subjects with missing evaluation, n (%)	5 (12.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.708
95% CI for the RR		(1.196, 2.439)
p-value for RR		0.0033

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.6.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 3		
Number of subjects with a response, n (%) [2]	4 (30.8)	5 (31.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.072
95% CI for the RR		(0.270, 4.265)
p-value for RR		0.9210
Day 8		
Number of subjects with a response, n (%) [2]	5 (38.5)	11 (68.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.887
95% CI for the RR		(0.647, 5.504)
p-value for RR		0.2449

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 15		
Number of subjects with a response, n (%) [2]	5 (38.5)	12 (75.0)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.059
95% CI for the RR		(0.669, 6.332)
p-value for RR		0.2077
Day 21		
Number of subjects with a response, n (%) [2]	4 (30.8)	12 (75.0)
Number of subjects with missing evaluation, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.574
95% CI for the RR		(0.743, 8.915)
p-value for RR		0.1359

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 45		
Number of subjects with a response, n (%) [2]	3 (23.1)	11 (68.8)
Number of subjects with missing evaluation, n (%)	3 (23.1)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		3.145
95% CI for the RR		(0.737, 13.428)
p-value for RR		0.1217

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	62	60
Day 3		
Number of subjects with a response, n (%) [2]	14 (22.6)	26 (43.3)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.832
95% CI for the RR		(1.091, 3.076)
p-value for RR		0.0220
Day 8		
Number of subjects with a response, n (%) [2]	27 (43.5)	36 (60.0)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.315
95% CI for the RR		(0.932, 1.856)
p-value for RR		0.1186

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 15		
Number of subjects with a response, n (%) [2]	31 (50.0)	41 (68.3)
Number of subjects with missing evaluation, n (%)	2 (3.2)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.305
95% CI for the RR		(0.972, 1.751)
p-value for RR		0.0763
Day 21		
Number of subjects with a response, n (%) [2]	34 (54.8)	40 (66.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.161
95% CI for the RR		(0.885, 1.522)
p-value for RR		0.2816

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 45		
Number of subjects with a response, n (%) [2]	34 (54.8)	47 (78.3)
Number of subjects with missing evaluation, n (%)	4 (6.5)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.364
95% CI for the RR		(1.065, 1.746)
p-value for RR		0.0140

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.6.2.1 .2 .2 .5 BMI

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	21	13
Day 3		
Number of subjects with a response, n (%) [2]	7 (33.3)	6 (46.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.397
95% CI for the RR		(0.642, 3.039)
p-value for RR		0.3995
Day 8		
Number of subjects with a response, n (%) [2]	10 (47.6)	8 (61.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.304
95% CI for the RR		(0.730, 2.329)
p-value for RR		0.3702

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 15		
Number of subjects with a response, n (%) [2]	11 (52.4)	8 (61.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.185
95% CI for the RR		(0.692, 2.031)
p-value for RR		0.5364
Day 21		
Number of subjects with a response, n (%) [2]	10 (47.6)	9 (69.2)
Number of subjects with missing evaluation, n (%)	2 (9.5)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.467
95% CI for the RR		(0.856, 2.512)
p-value for RR		0.1631

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 45		
Number of subjects with a response, n (%) [2]	9 (42.9)	9 (69.2)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.630
95% CI for the RR		(0.926, 2.869)
p-value for RR		0.0905

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 3		
Number of subjects with a response, n (%) [2]	1 (5.0)	11 (52.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		10.377
95% CI for the RR		(1.451, 74.228)
p-value for RR		0.0198
Day 8		
Number of subjects with a response, n (%) [2]	6 (30.0)	16 (76.2)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.516
95% CI for the RR		(1.233, 5.131)
p-value for RR		0.0112

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	8 (40.0)	17 (81.0)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.005
95% CI for the RR		(1.126, 3.568)
p-value for RR		0.0180
Day 21		
Number of subjects with a response, n (%) [2]	9 (45.0)	16 (76.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.677
95% CI for the RR		(0.978, 2.877)
p-value for RR		0.0604

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 45		
Number of subjects with a response, n (%) [2]	11 (55.0)	18 (85.7)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.544
95% CI for the RR		(1.000, 2.383)
p-value for RR		0.0499

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 3		
Number of subjects with a response, n (%) [2]	10 (29.4)	14 (33.3)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.048
95% CI for the RR		(0.549, 2.001)
p-value for RR		0.8867
Day 8		
Number of subjects with a response, n (%) [2]	16 (47.1)	23 (54.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.076
95% CI for the RR		(0.685, 1.692)
p-value for RR		0.7503

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 15		
Number of subjects with a response, n (%) [2]	17 (50.0)	28 (66.7)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.233
95% CI for the RR		(0.836, 1.820)
p-value for RR		0.2912
Day 21		
Number of subjects with a response, n (%) [2]	19 (55.9)	27 (64.3)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.064
95% CI for the RR		(0.757, 1.494)
p-value for RR		0.7209

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 45		
Number of subjects with a response, n (%) [2]	17 (50.0)	31 (73.8)
Number of subjects with missing evaluation, n (%)	4 (11.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.365
95% CI for the RR		(0.973, 1.915)
p-value for RR		0.0715

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.6.2.1 .2 .2 .6 Beginn der PPD

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	32	32
Day 3		
Number of subjects with a response, n (%) [2]	8 (25.0)	18 (56.3)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.167
95% CI for the RR		(1.121, 4.189)
p-value for RR		0.0215
Day 8		
Number of subjects with a response, n (%) [2]	16 (50.0)	24 (75.0)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.445
95% CI for the RR		(0.962, 2.168)
p-value for RR		0.0759

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 15		
Number of subjects with a response, n (%) [2]	15 (46.9)	23 (71.9)
Number of subjects with missing evaluation, n (%)	1 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.477
95% CI for the RR		(0.968, 2.253)
p-value for RR		0.0706
Day 21		
Number of subjects with a response, n (%) [2]	17 (53.1)	22 (68.8)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.246
95% CI for the RR		(0.847, 1.833)
p-value for RR		0.2635

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 45		
Number of subjects with a response, n (%) [2]	20 (62.5)	26 (81.3)
Number of subjects with missing evaluation, n (%)	3 (9.4)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.252
95% CI for the RR		(0.925, 1.695)
p-value for RR		0.1460

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 3		
Number of subjects with a response, n (%) [2]	10 (23.3)	13 (29.5)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.196
95% CI for the RR		(0.603, 2.374)
p-value for RR		0.6086
Day 8		
Number of subjects with a response, n (%) [2]	16 (37.2)	23 (52.3)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.323
95% CI for the RR		(0.826, 2.117)
p-value for RR		0.2439

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	21 (48.8)	30 (68.2)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.314
95% CI for the RR		(0.921, 1.876)
p-value for RR		0.1320
Day 21		
Number of subjects with a response, n (%) [2]	21 (48.8)	30 (68.2)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.314
95% CI for the RR		(0.931, 1.856)
p-value for RR		0.1203

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	17 (39.5)	32 (72.7)
Number of subjects with missing evaluation, n (%)	4 (9.3)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.732
95% CI for the RR		(1.175, 2.553)
p-value for RR		0.0055

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.6.2.1 .2 .2 .7 PPD in der Familie

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 3		
Number of subjects with a response, n (%) [2]	0	2 (20.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		5.00
95% CI for the RR		(0.270, 92.622)
p-value for RR		0.2799
Day 8		
Number of subjects with a response, n (%) [2]	4 (40.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.50
95% CI for the RR		(0.602, 3.735)
p-value for RR		0.3837

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	4 (40.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.75
95% CI for the RR		(0.740, 4.139)
p-value for RR		0.2026
Day 21		
Number of subjects with a response, n (%) [2]	5 (50.0)	9 (90.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.80
95% CI for the RR		(0.937, 3.459)
p-value for RR		0.0778

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	6 (60.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.17
95% CI for the RR		(0.610, 2.232)
p-value for RR		0.6414

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	65	66
Day 3		
Number of subjects with a response, n (%) [2]	18 (27.7)	29 (43.9)
Number of subjects with missing evaluation, n (%)	1 (1.5)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.59
95% CI for the RR		(0.984, 2.559)
p-value for RR		0.0584
Day 8		
Number of subjects with a response, n (%) [2]	28 (43.1)	41 (62.1)
Number of subjects with missing evaluation, n (%)	1 (1.5)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.44
95% CI for the RR		(1.030, 2.020)
p-value for RR		0.0333

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	32 (49.2)	46 (69.7)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.42
95% CI for the RR		(1.055, 1.899)
p-value for RR		0.0203
Day 21		
Number of subjects with a response, n (%) [2]	33 (50.8)	43 (65.2)
Number of subjects with missing evaluation, n (%)	2 (3.1)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.28
95% CI for the RR		(0.953, 1.728)
p-value for RR		0.1002

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	31 (47.7)	51 (77.3)
Number of subjects with missing evaluation, n (%)	6 (9.2)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.62
95% CI for the RR		(1.217, 2.157)
p-value for RR		0.0010

NOTE 1: Normal approximation method has been used to estimate relative risk, odds ratio, and absolute risk reduction.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.6.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 3		
Number of subjects with a response, n (%) [2]	16 (27.1)	25 (37.9)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.336
95% CI for the RR		(0.806, 2.214)
p-value for RR		0.2605
Day 8		
Number of subjects with a response, n (%) [2]	28 (47.5)	41 (62.1)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.252
95% CI for the RR		(0.905, 1.733)
p-value for RR		0.1749

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	32 (54.2)	47 (71.2)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.256
95% CI for the RR		(0.957, 1.648)
p-value for RR		0.0999
Day 21		
Number of subjects with a response, n (%) [2]	31 (52.5)	45 (68.2)
Number of subjects with missing evaluation, n (%)	1 (1.7)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.241
95% CI for the RR		(0.941, 1.638)
p-value for RR		0.1266

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	31 (52.5)	52 (78.8)
Number of subjects with missing evaluation, n (%)	5 (8.5)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.435
95% CI for the RR		(1.116, 1.844)
p-value for RR		0.0049

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	16	10
Day 3		
Number of subjects with a response, n (%) [2]	2 (12.5)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		4.261
95% CI for the RR		(1.122, 16.185)
p-value for RR		0.0333
Day 8		
Number of subjects with a response, n (%) [2]	4 (25.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.130
95% CI for the RR		(0.790, 5.747)
p-value for RR		0.1353

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	4 (25.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.130
95% CI for the RR		(0.800, 5.669)
p-value for RR		0.1300
Day 21		
Number of subjects with a response, n (%) [2]	7 (43.8)	7 (70.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.420
95% CI for the RR		(0.725, 2.780)
p-value for RR		0.3061

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	6 (37.5)	6 (60.0)
Number of subjects with missing evaluation, n (%)	2 (12.5)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.420
95% CI for the RR		(0.676, 2.983)
p-value for RR		0.3542

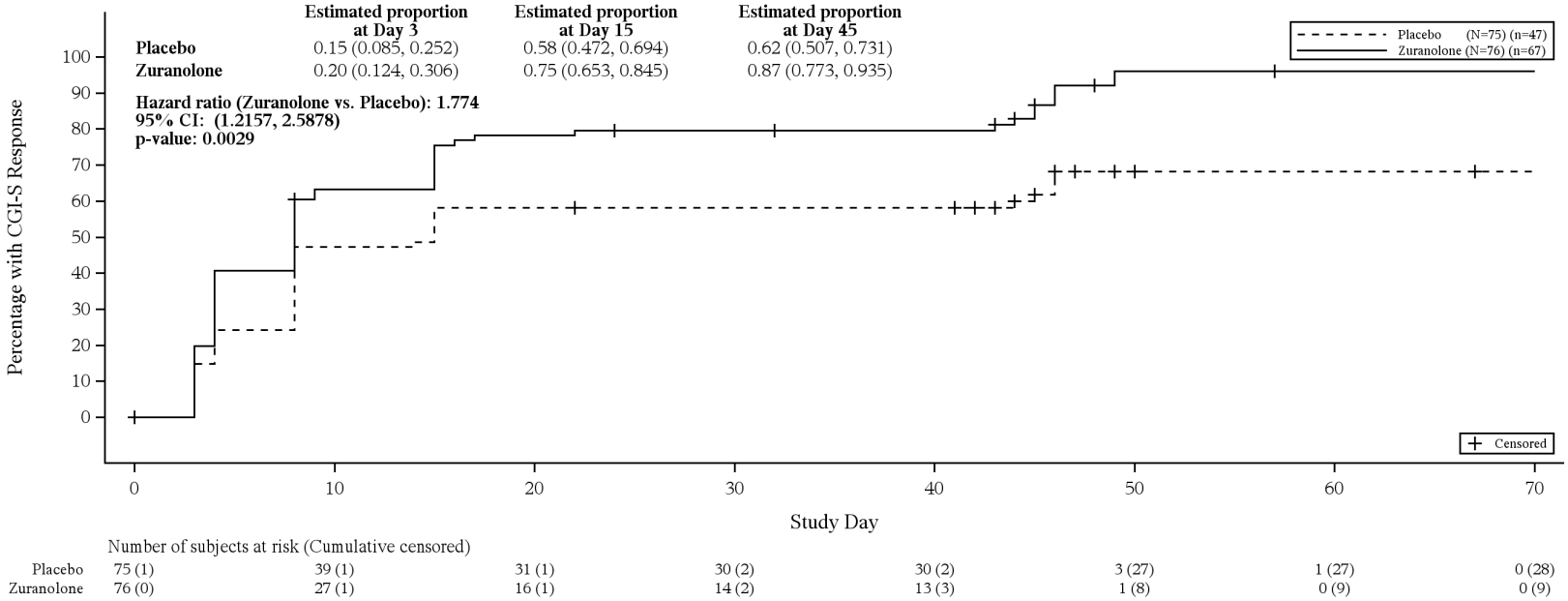
NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
[2] Number of subjects with a CGI-S response (1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-201-by.sas:t-cgis-resp15-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.6.2.2 TTE-Analysen

4.6.2.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.
NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-ovr.sas:f-cgis-resp15-tte-201-ovr-itta.rtf **Run Date:** 15DEC2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	75	76
Number of subjects with response, n (%) [2]	47 (62.7)	67 (88.2)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0 , 45.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	15.0 (15.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.774
95% CI for the HR		(1.2157 , 2.5878)
p-value for the HR		0.0029

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-ovr.sas:t-cgis-resp15-tte-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.6.2.2 .2 Subgruppen

4.6.2.2 .2 .1 Interaktionstest

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	75	76	
Number of subjects with response, n (%)	47 (62.7)	67 (88.2)	
Age Group (years)			
18 - 24, n / N (%)	15/25 (60.0)	14/17 (82.4)	0.7447
25 - 45, n / N (%)	32/50 (64.0)	53/59 (89.8)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	14/22 (63.6)	24/30 (80.0)	0.1139
>=28, n / N (%)	33/53 (62.3)	43/46 (93.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	23/32 (71.9)	27/31 (87.1)	0.1464
White, n / N (%)	23/40 (57.5)	39/44 (88.6)	
Antidepressant Use at Baseline			
Yes, n / N (%)	7/13 (53.8)	14/16 (87.5)	0.6389
No, n / N (%)	40/62 (64.5)	53/60 (88.3)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-int.sas:t-cgis-resp15-tte-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	12/21 (57.1)	12/13 (92.3)	0.3604(a)
25-29.9, n / N (%)	12/20 (60.0)	19/21 (90.5)	0.2463(b)
>=30, n / N (%)	23/34 (67.6)	36/42 (85.7)	0.0209(c)
Onset of PPD			
3rd Trimester, n / N (%)	23/32 (71.9)	30/32 (93.8)	0.8486
Postpartum, n / N (%)	24/43 (55.8)	37/44 (84.1)	
Family History of PPD			
Yes, n / N (%)	7/10 (70.0)	9/10 (90.0)	0.5019
No/Unknown, n / N (%)	40/65 (61.5)	58/66 (87.9)	
History of PPD			
1st Episode, n / N (%)	40/59 (67.8)	59/66 (89.4)	0.3182
Recurrent Episode, n / N (%)	7/16 (43.8)	8/10 (80.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	6/8 (75.0)	9/10 (90.0)	NA
>=20, n / N (%)	41/67 (61.2)	58/66 (87.9)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-int.sas:t-cgis-resp15-tte-201-int-itta.rtf **Run Date:** 29JUL2025

4.6.2.2 .2 .2 Subgruppenanalysen

4.6.2.2 .2 .2 .1 Alter

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

	Placebo (N=26)	**Zuranolone (N=18)**
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	15 (60.0)	14 (82.4)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 15.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0, NE)	4.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (44.0, NE)	15.0 (4.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.662
95% CI for the HR		(0.7774 , 3.5514)
p-value for the HR		0.1902

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	50	59
Number of subjects with response, n (%) [2]	32 (64.0)	53 (89.8)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 45.0)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	16.0 (15.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.716
95% CI for the HR		(1.1025 , 2.6704)
p-value for the HR		0.0167

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.6.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	14 (63.6)	24 (80.0)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	11.5 (4.0, NE)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	44.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.038
95% CI for the HR		(0.5244 , 2.0545)
p-value for the HR		0.9148

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	53	46
Number of subjects with response, n (%) [2]	33 (62.3)	43 (93.5)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0 , 46.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	15.0 (8.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.199
95% CI for the HR		(1.3810 , 3.5028)
p-value for the HR		0.0009

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.6.2.2 .2 .2 .3 Abstammung

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	32	31
Number of subjects with response, n (%) [2]	23 (71.9)	27 (87.1)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (4.0 , 15.0)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (14.0, NE)	43.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.237
95% CI for the HR		(0.7068 , 2.1639)
p-value for the HR		0.4567

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-201B - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	23 (57.5)	39 (88.6)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	44.0 (8.0, NE)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	15.0 (8.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.269
95% CI for the HR		(1.3260 , 3.8822)
p-value for the HR		0.0028

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.6.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	7 (53.8)	14 (87.5)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 45.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	45.0 (3.0, NE)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (8.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.017
95% CI for the HR		(0.7874 , 5.1672)
p-value for the HR		0.1438

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 2 of 2

Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	62	60
Number of subjects with response, n (%) [2]	40 (64.5)	53 (88.3)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0 , 44.0)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	16.5 (15.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.704
95% CI for the HR		(1.1265 , 2.5779)
p-value for the HR		0.0116

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.6.2.2 .2 .2 .5 BMI

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

Page: 1 of 3

BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	21	13
Number of subjects with response, n (%) [2]	12 (57.1)	12 (92.3)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (4.0, NE)	8.0 (4.0 , 16.0)
75th percentile - Q3 (95% CI)	NE (8.0, NE)	16.0 (4.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.942
95% CI for the HR		(0.8659 , 4.3557)
p-value for the HR		0.1073

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	12 (60.0)	19 (90.5)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 15.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	45.0 (8.0, NE)	4.0 (3.0 , 8.0)
75th percentile - Q3 (95% CI)	46.0 (46.0, NE)	9.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.646
95% CI for the HR		(1.6399 , 8.1052)
p-value for the HR		0.0015

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	23 (67.6)	36 (85.7)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	43.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.192
95% CI for the HR		(0.7012 , 2.0278)
p-value for the HR		0.5160

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.6.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	32	32
Number of subjects with response, n (%) [2]	23 (71.9)	30 (93.8)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 44.0)	4.0 (3.0 , 8.0)
75th percentile - Q3 (95% CI)	46.0 (15.0, NE)	9.0 (8.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.800
95% CI for the HR		(1.0342 , 3.1317)
p-value for the HR		0.0376

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	24 (55.8)	37 (84.1)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (4.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0, NE)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	22.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.733
95% CI for the HR		(1.0286 , 2.9207)
p-value for the HR		0.0389

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.6.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	7 (70.0)	9 (90.0)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 15.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0, NE)	8.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	46.0 (15.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.736
95% CI for the HR		(1.0117 , 13.7984)
p-value for the HR		0.0480

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	65	66
Number of subjects with response, n (%) [2]	40 (61.5)	58 (87.9)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	14.5 (8.0 , 45.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	16.0 (9.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.656
95% CI for the HR		(1.0998 , 2.4929)
p-value for the HR		0.0157

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.6.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	40 (67.8)	59 (89.4)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 44.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	NE (44.0, NE)	15.0 (9.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.648
95% CI for the HR		(1.0963 , 2.4781)
p-value for the HR		0.0163

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-201-by.sas:t-cgis-resp15-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	16	10
Number of subjects with response, n (%) [2]	7 (43.8)	8 (80.0)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 15.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	NE (8.0, NE)	4.0 (3.0 , 22.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	22.0 (4.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.645
95% CI for the HR		(0.8988 , 7.7820)
p-value for the HR		0.0774

NOTE 1: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-S score at Baseline. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

[2] Number of subjects with a CGI-S response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

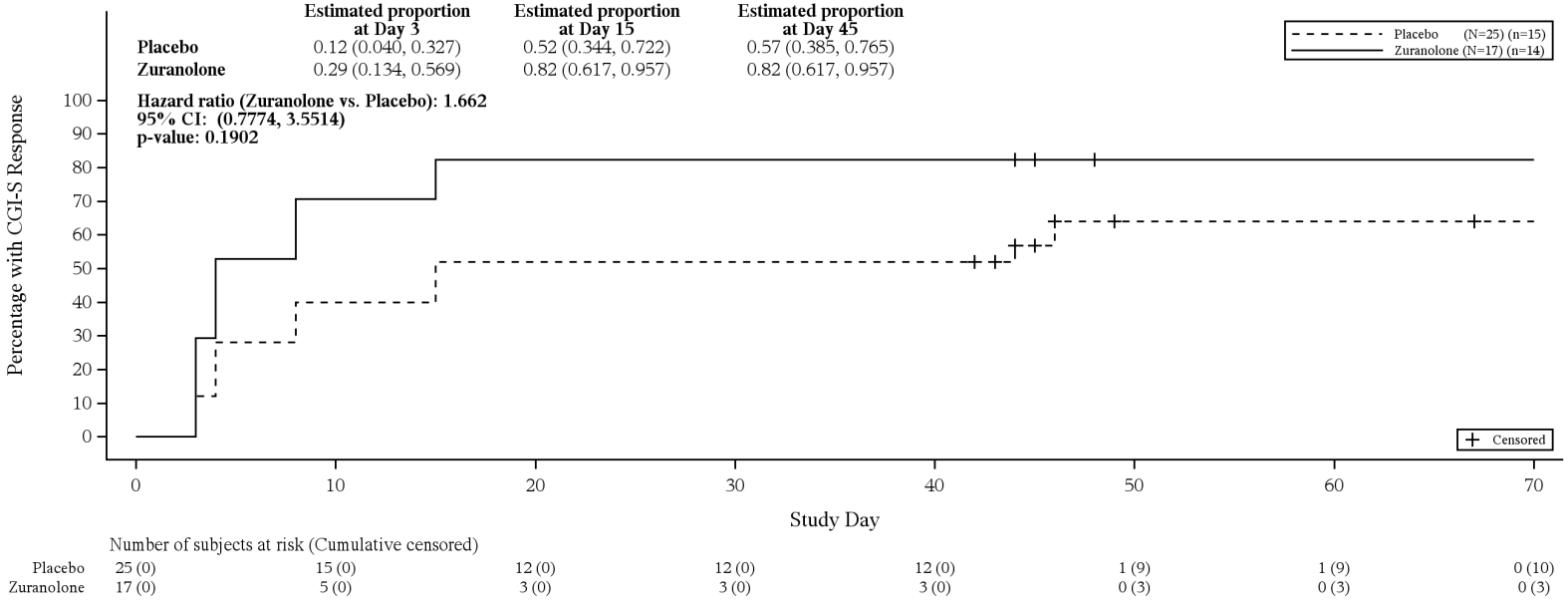
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4.6.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

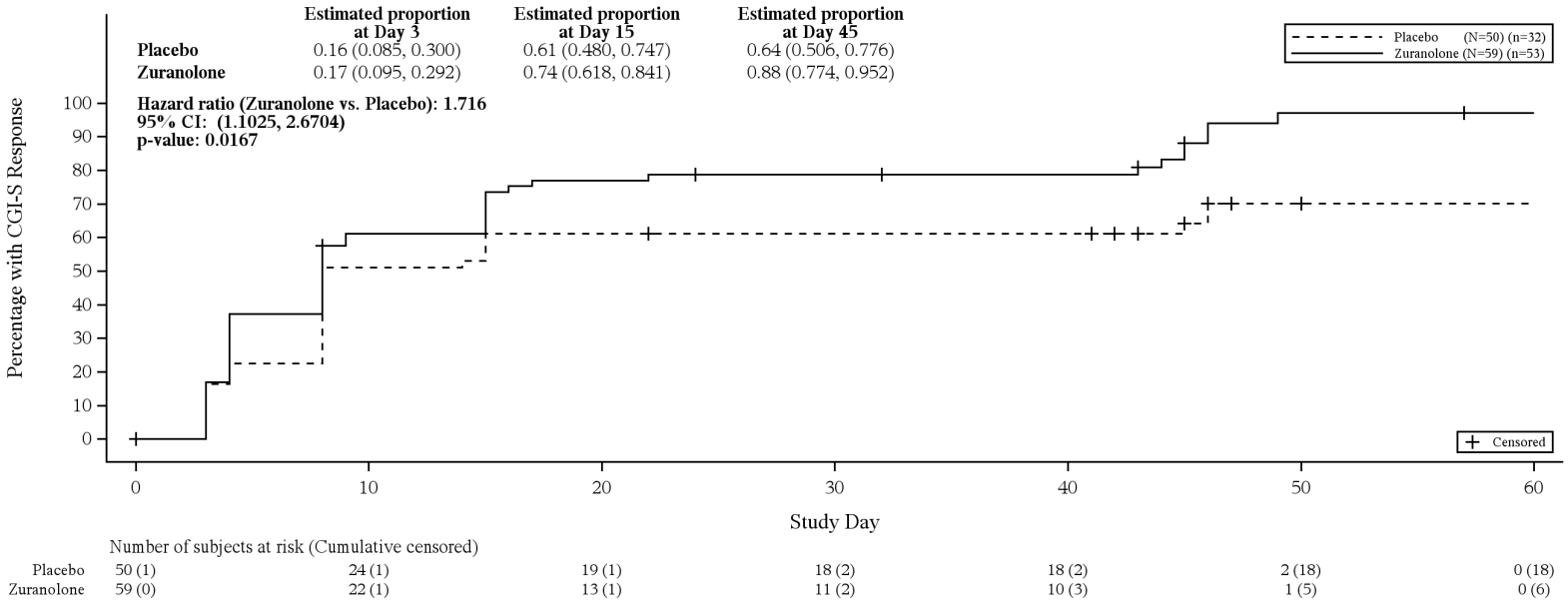
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

Page: 2 of 17

Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

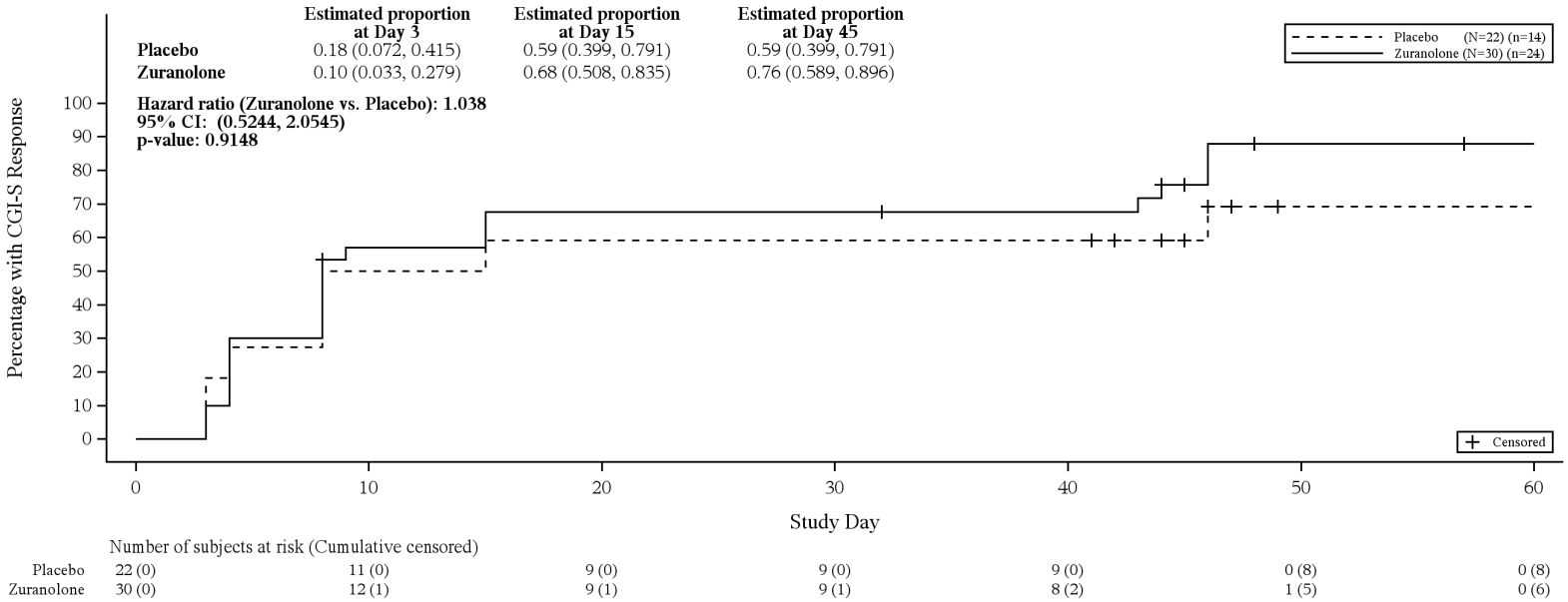
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

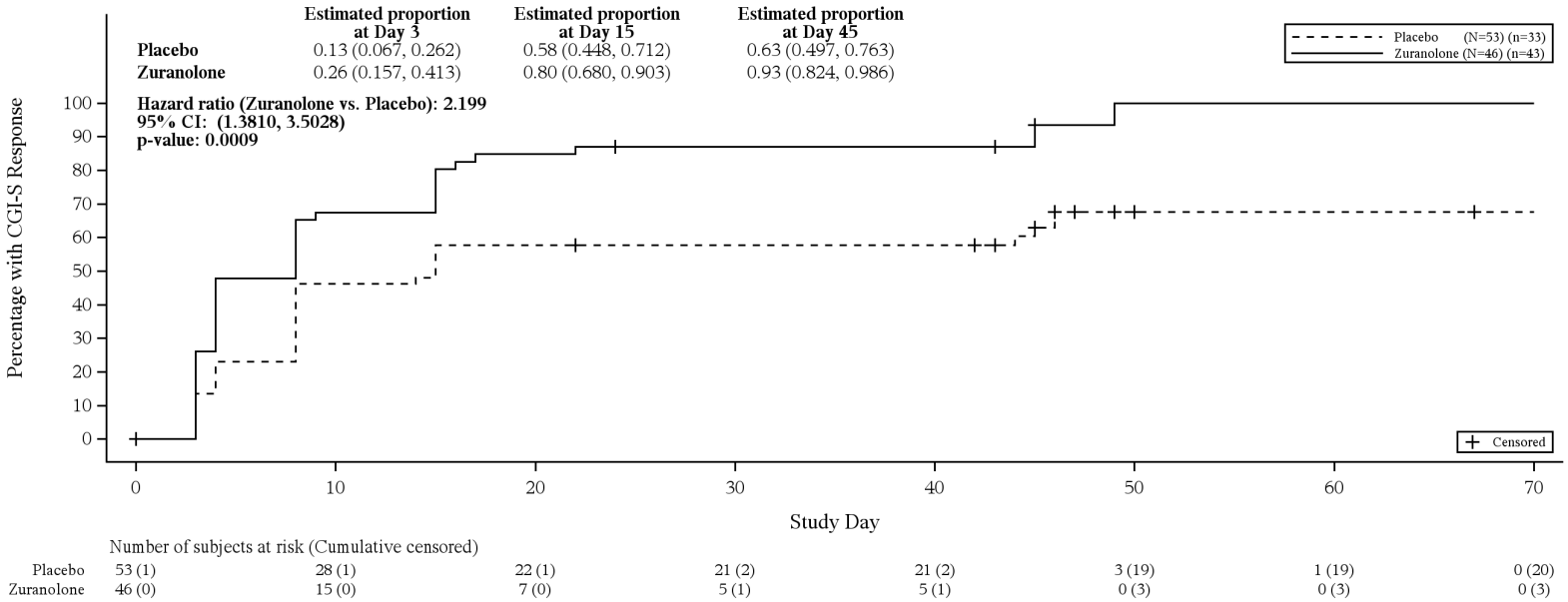
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

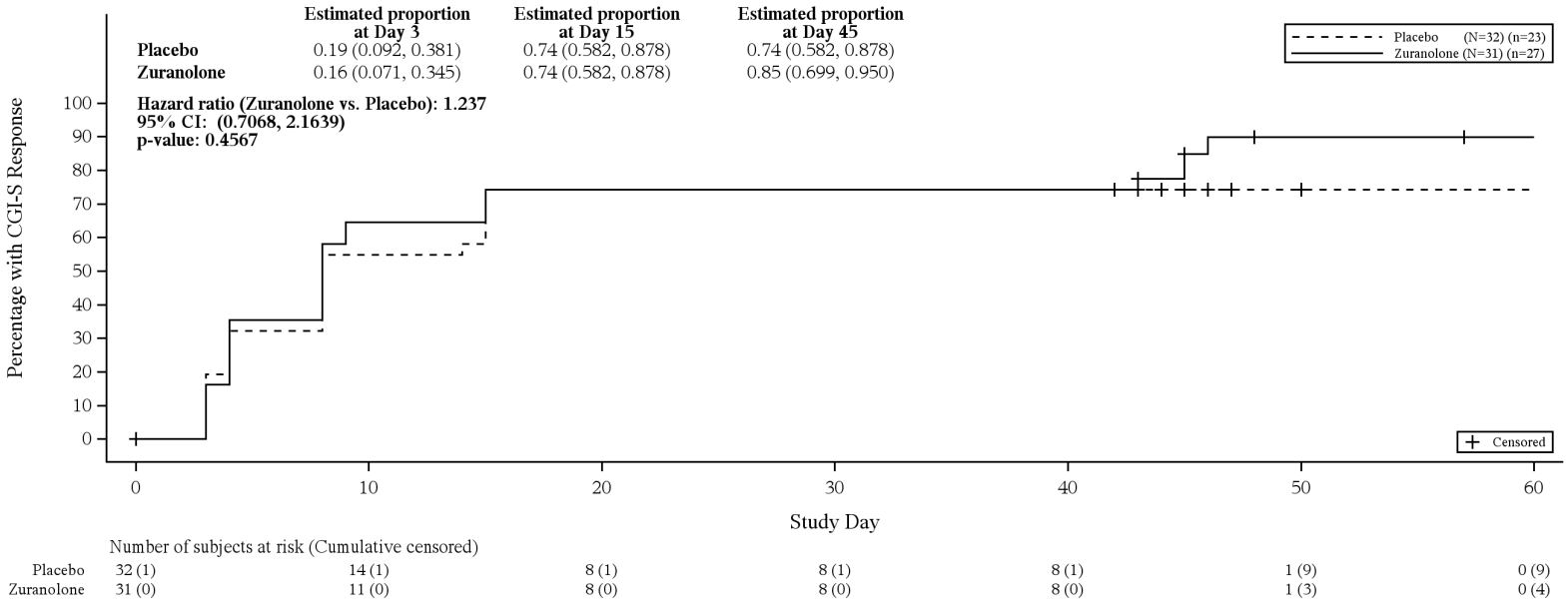
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

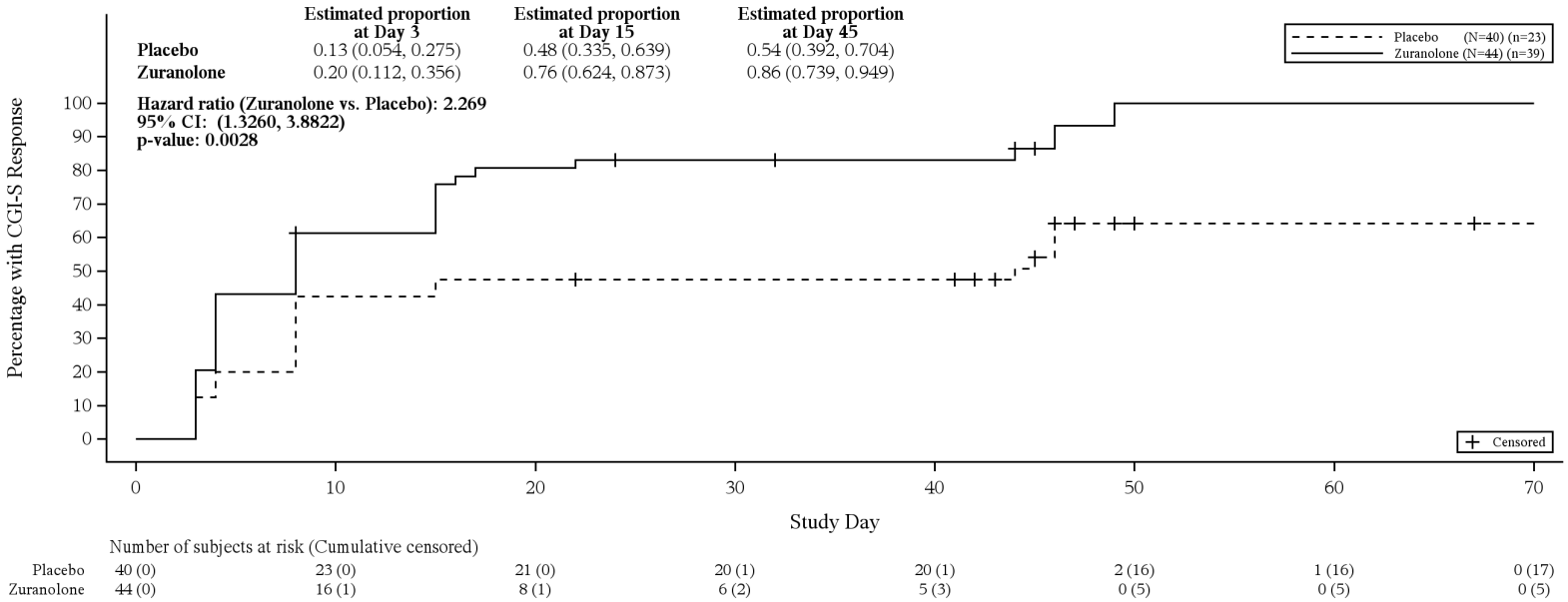
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

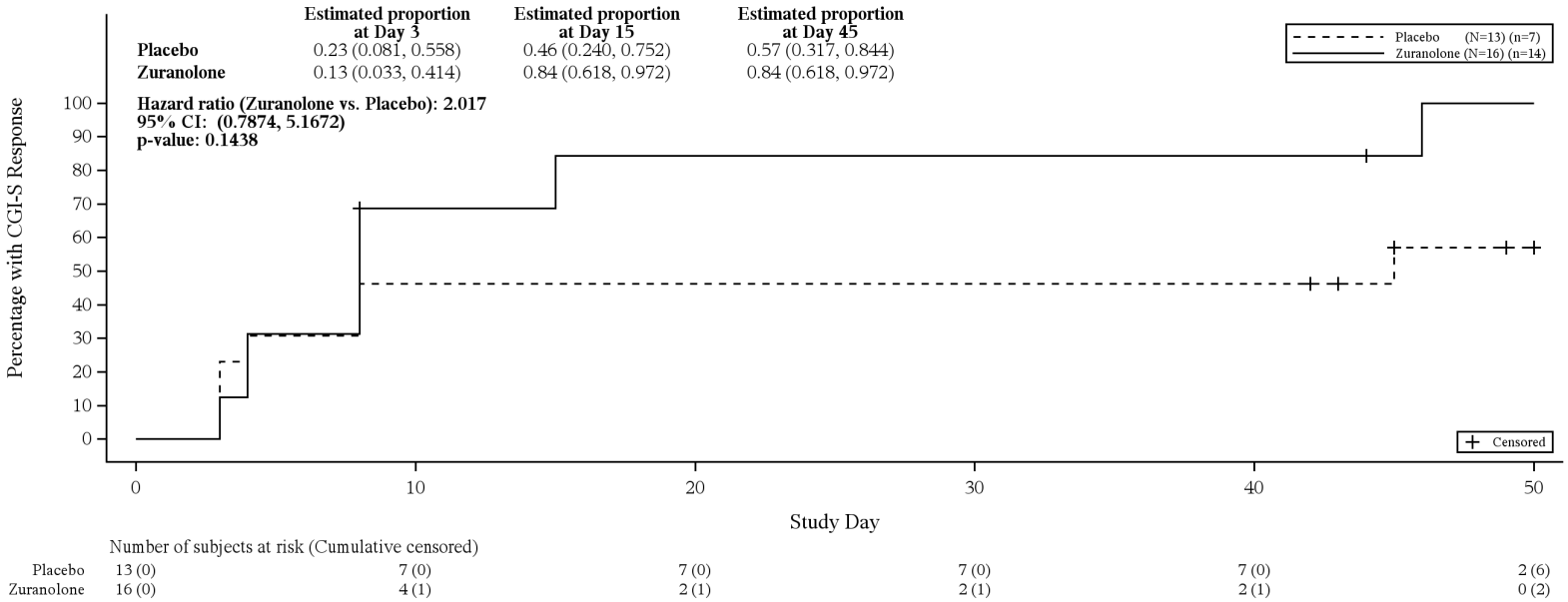
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

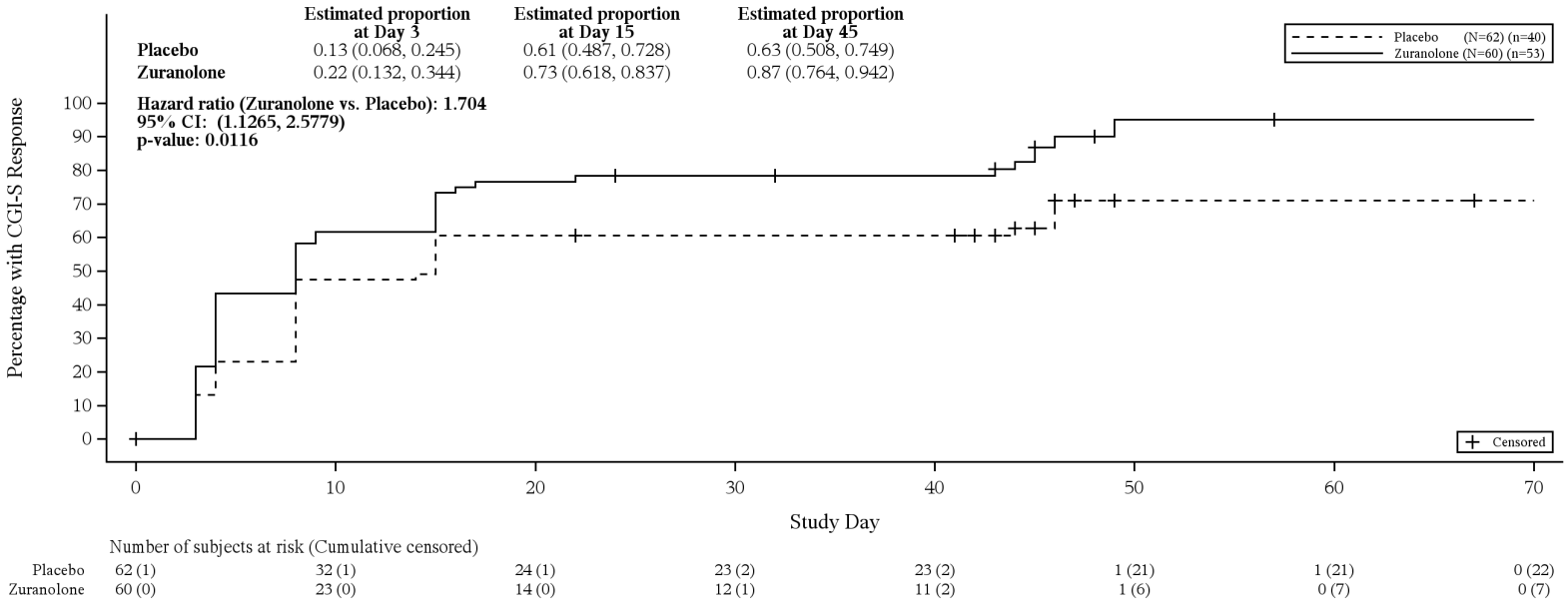
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

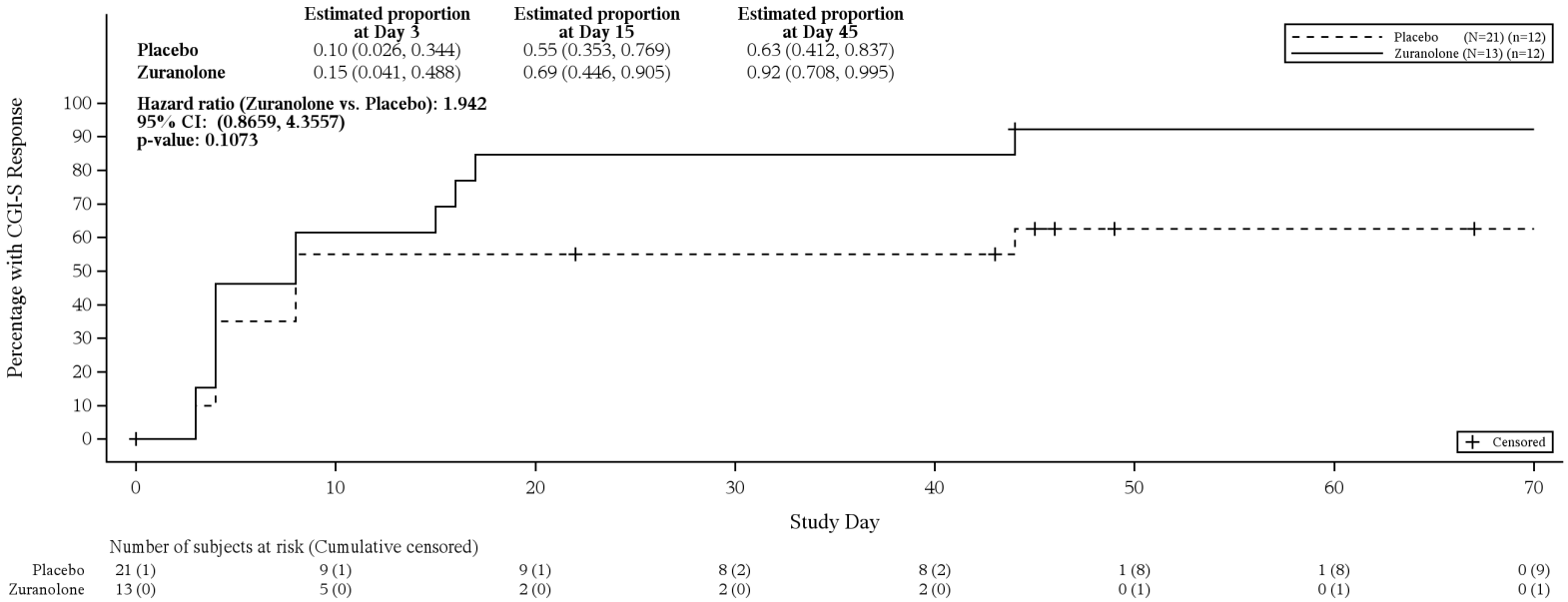
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

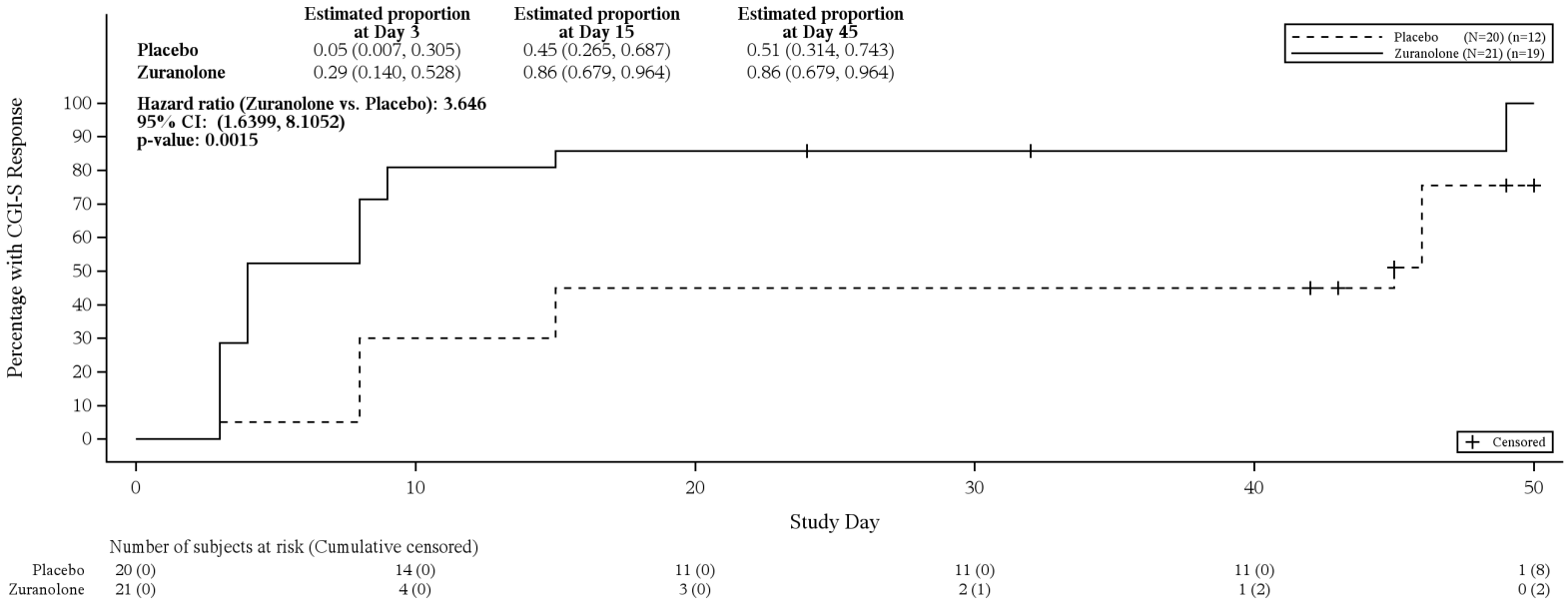
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

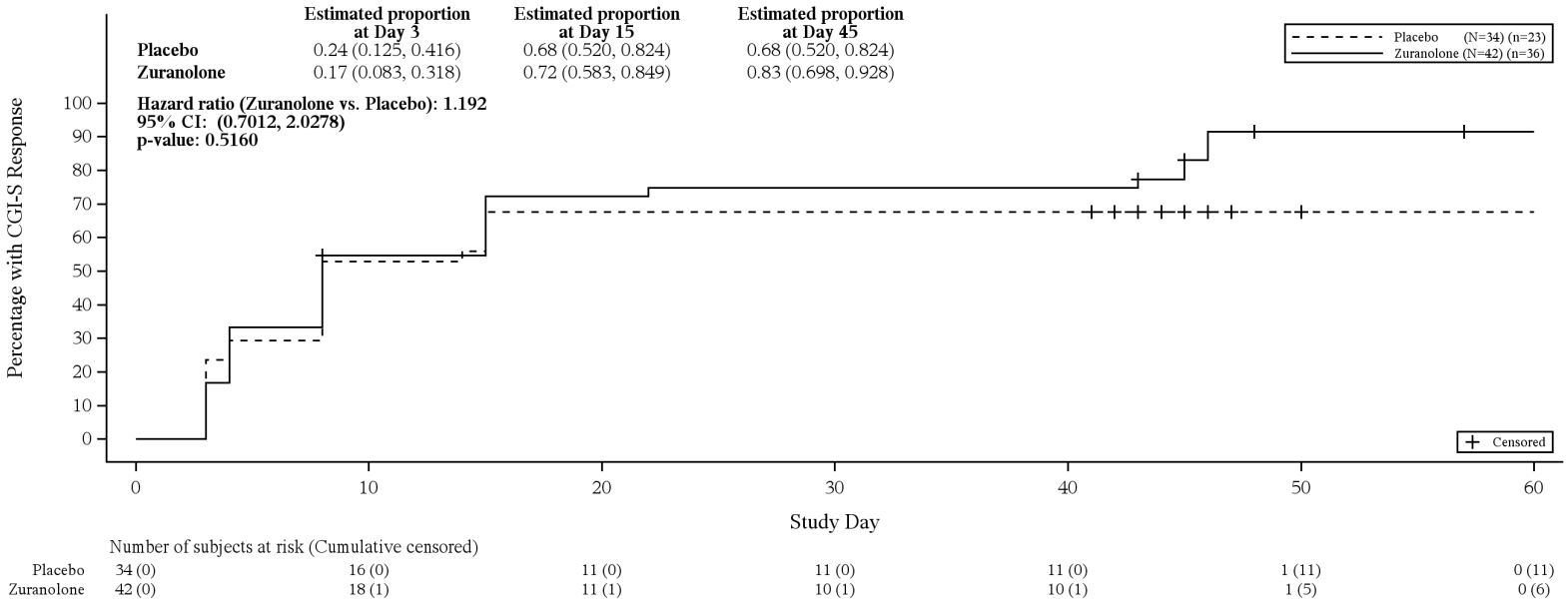
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

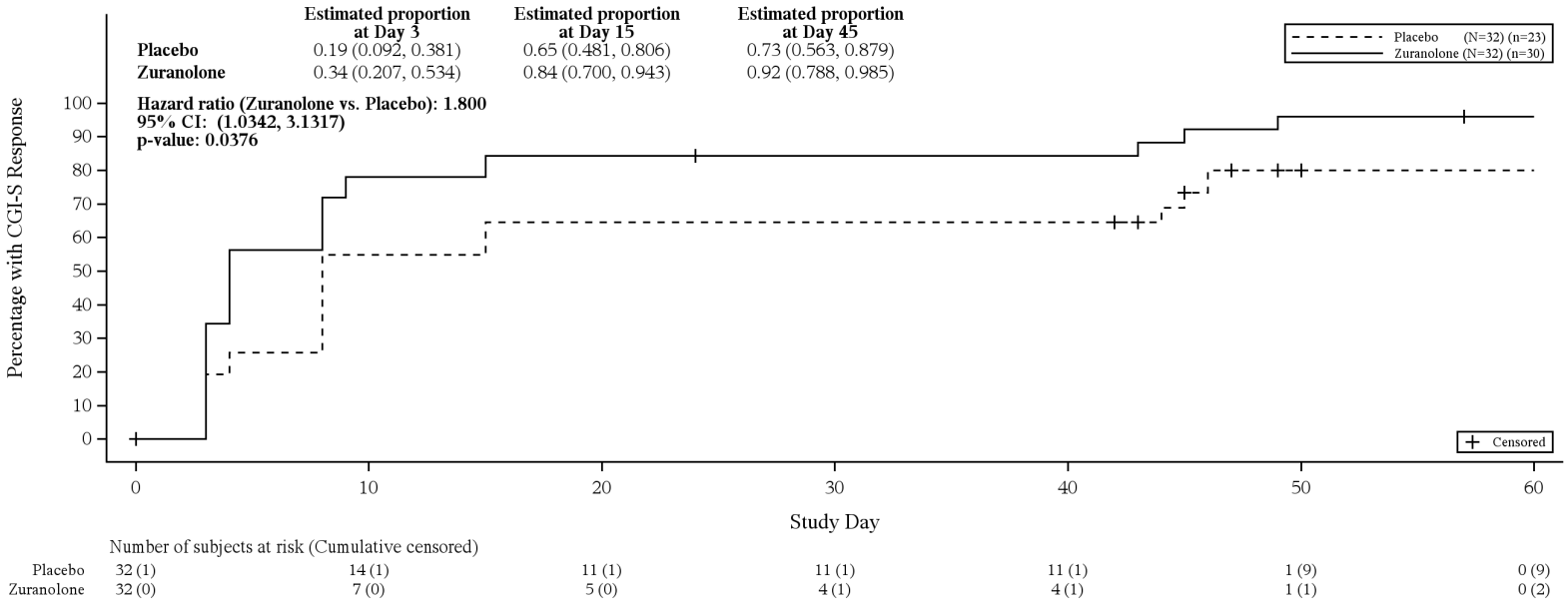
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

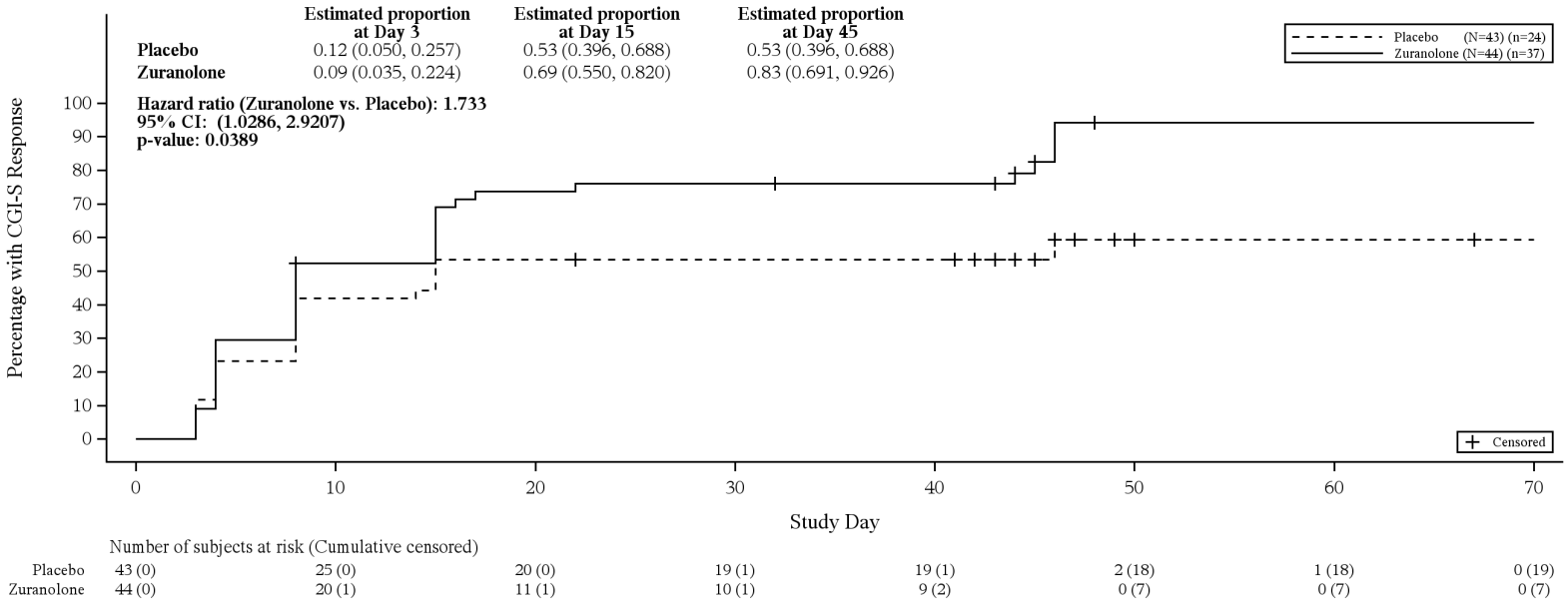
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

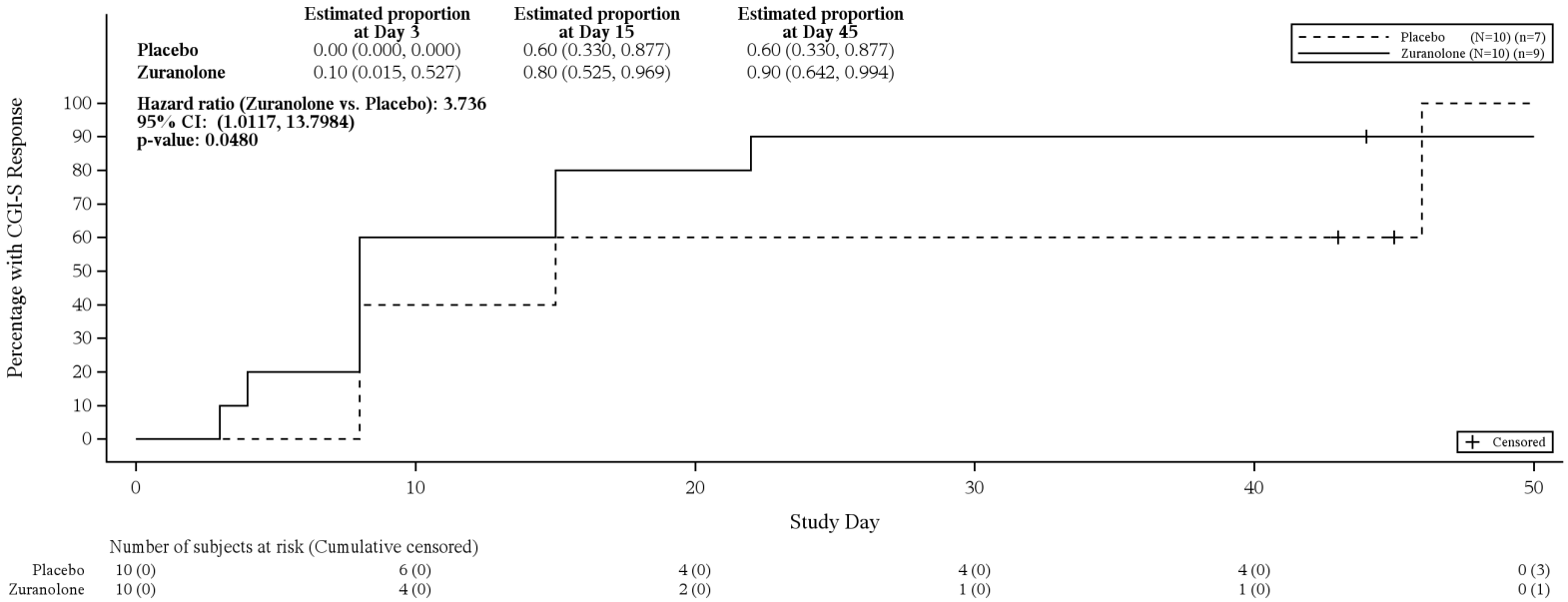
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

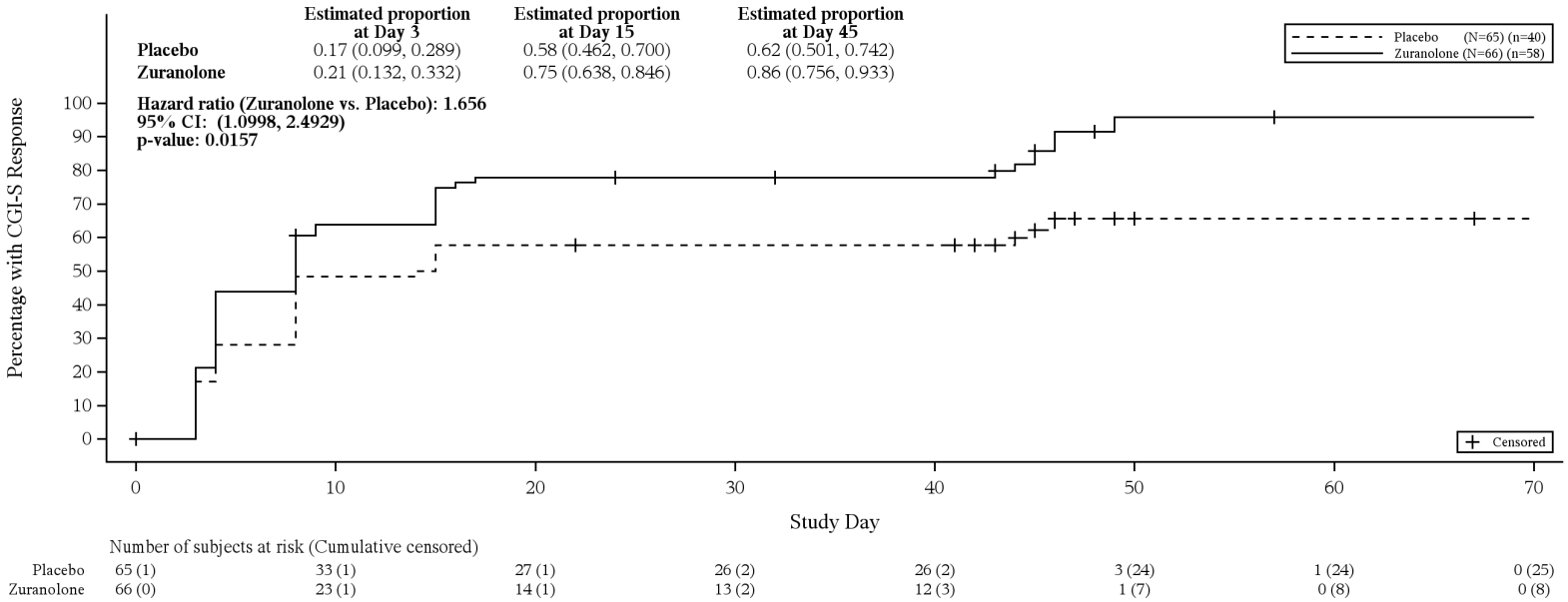
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

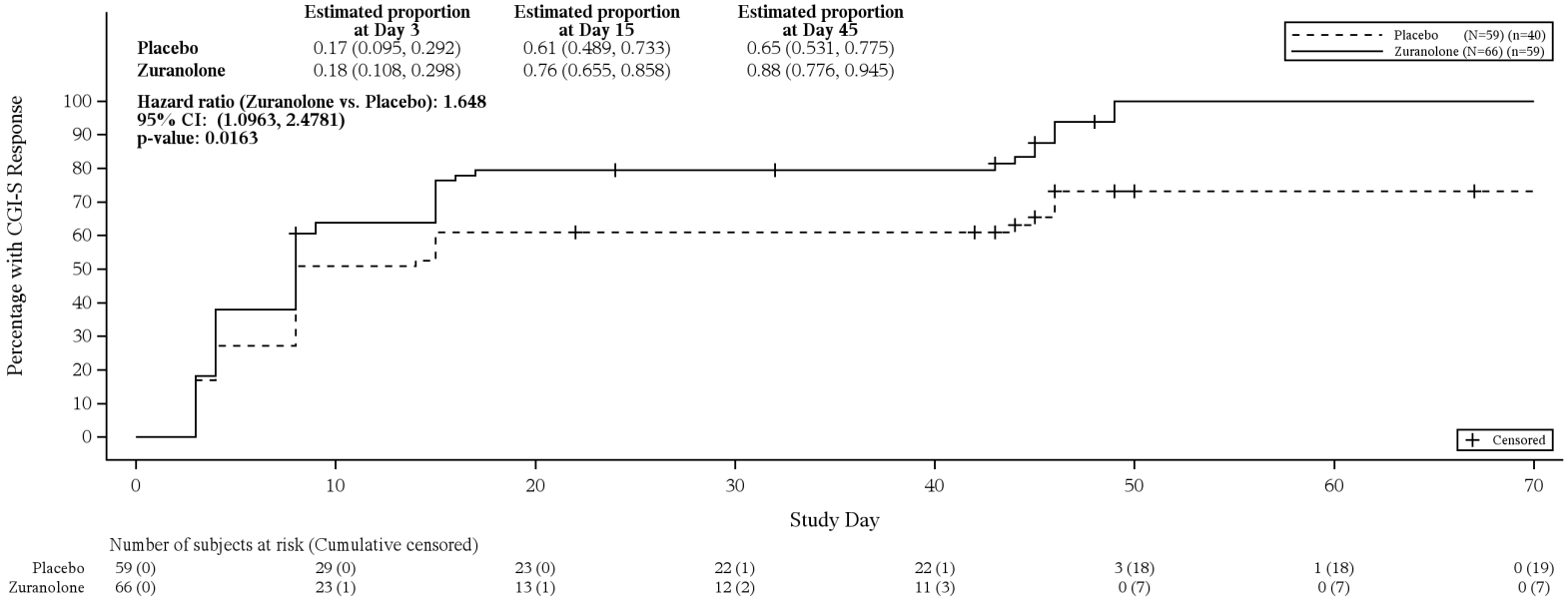
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

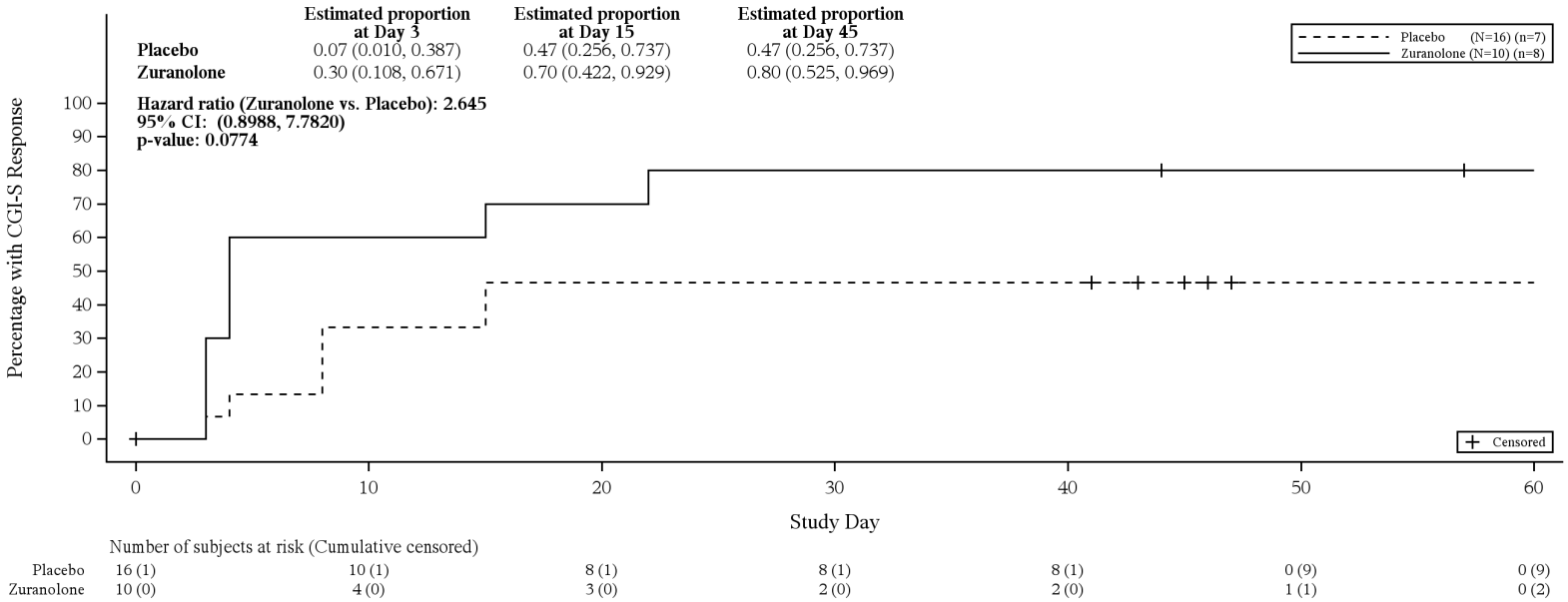
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-S score at Baseline are included in the analysis. Baseline is defined as the last non-missing evaluation prior to the first dose of investigational product.

NOTE 2: CGI-S response is defined as 1.05 points (15% of total scale range 0-7) or greater reduction in total score from baseline. Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-201-by.sas:f-cgis-resp15-tte-201-by-itta.rtf **Run Date:** 08JAN2026

4.7 CGI-I

4.7.1 MMRM

Model-based Results on Change from Baseline in Clinical Global Impression - Improvement (CGI-I): 217-PPD-201B - ITT population

Page: 1 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 3		
n	74	74
LS Mean (SE)	-0.95 (0.114)	-1.16 (0.114)
95% CI for the LS Mean	-1.18, -0.73	-1.39, -0.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.21 (0.161)
95% CI for the LS Mean		-0.53, 0.11
p-value		0.1898
Hedges' g (Zuranolone vs. Placebo)		-0.215
95% CI for Hedges' g		-0.5386, 0.1077
Day 8		
n	74	75
LS Mean (SE)	-1.40 (0.127)	-1.84 (0.127)
95% CI for the LS Mean	-1.65, -1.15	-2.09, -1.59
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.44 (0.180)
95% CI for the LS Mean		-0.80, -0.09
p-value		0.0147
Hedges' g (Zuranolone vs. Placebo)		-0.403
95% CI for Hedges' g		-0.7270, -0.0783

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Baseline CGI-I score is designated as 4 for change from baseline derivation.

Source: biib125/v_a/germany_amnog/t-cgii-mmrm-201-ovr.sas:t-cgii-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Clinical Global Impression - Improvement (CGI-I): 217-PPD-201B - ITT population

Page: 2 of 3

	Placebo (N=76)	Zuranolone (N=77)
Day 15		
n	73	74
LS Mean (SE)	-1.58 (0.132)	-1.91 (0.131)
95% CI for the LS Mean	-1.84, -1.32	-2.17, -1.65
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.33 (0.186)
95% CI for the LS Mean		-0.70, 0.04
p-value		0.0785
Hedges' g (Zuranolone vs. Placebo)		-0.291
95% CI for Hedges' g		-0.6158, 0.0342
Day 21		
n	73	74
LS Mean (SE)	-1.58 (0.142)	-1.92 (0.141)
95% CI for the LS Mean	-1.87, -1.30	-2.20, -1.65
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.34 (0.200)
95% CI for the LS Mean		-0.74, 0.06
p-value		0.0919
Hedges' g (Zuranolone vs. Placebo)		-0.278
95% CI for Hedges' g		-0.6033, 0.0465

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Baseline CGI-I score is designated as 4 for change from baseline derivation.

Source: biib125/v_a/germany_amnog/t-cgii-mmrm-201-ovr.sas:t-cgii-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

Model-based Results on Change from Baseline in Clinical Global Impression - Improvement (CGI-I): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Day 45		
n	68	73
LS Mean (SE)	-1.61 (0.135)	-2.11 (0.131)
95% CI for the LS Mean	-1.87, -1.34	-2.37, -1.85
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.51 (0.188)
95% CI for the LS Mean		-0.88, -0.14
p-value		0.0078
Hedges' g (Zuranolone vs. Placebo)		-0.453
95% CI for Hedges' g		-0.7871, -0.1181

NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Baseline CGI-I score is designated as 4 for change from baseline derivation.

Source: biib125/v_a/germany_amnog/t-cgii-mmrm-201-ovr.sas:t-cgii-mmrm-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.7.2 Ansprechen

4.7.2.1 Responder-Analysen

4.7.2.1 .1 ITT-Population

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-201B - ITT population

Page: 1 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Number of evaluable subjects [1]	74	76
Day 3		
Number of subjects with a response, n (%) [2]	21 (28.4)	28 (36.8)
Number of subjects with missing evaluation, n (%)	0	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.297
95% CI for the RR		(0.814, 2.067)
p-value for RR		0.2732
OR - Odds Ratio (Zuranolone vs. Placebo)		1.403
95% CI for the OR		(0.709, 2.778)
p-value for OR		0.3312
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.070
95% CI for the ARR		(-0.075, 0.215)
p-value for ARR		0.3450

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-ovr.sas:t-cgii-resp12-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-201B - ITT population

Page: 2 of 5

Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 8		
Number of subjects with a response, n (%) [2]	37 (50.0)	49 (64.5)
Number of subjects with missing evaluation, n (%)	0	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.294
95% CI for the RR		(0.976, 1.715)
p-value for RR		0.0733
OR - Odds Ratio (Zuranolone vs. Placebo)		1.771
95% CI for the OR		(0.910, 3.448)
p-value for OR		0.0925
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.136
95% CI for the ARR		(-0.020, 0.291)
p-value for ARR		0.0868

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-ovr.sas:t-cgii-resp12-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 15		
Number of subjects with a response, n (%) [2]	38 (51.4)	53 (69.7)
Number of subjects with missing evaluation, n (%)	1 (1.4)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.355
95% CI for the RR		(1.038, 1.769)
p-value for RR		0.0257
OR - Odds Ratio (Zuranolone vs. Placebo)		2.134
95% CI for the OR		(1.080, 4.217)
p-value for OR		0.0291
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.172
95% CI for the ARR		(0.018, 0.327)
p-value for ARR		0.0290

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-ovr.sas:t-cgii-resp12-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 21		
Number of subjects with a response, n (%) [2]	40 (54.1)	52 (68.4)
Number of subjects with missing evaluation, n (%)	1 (1.4)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.266
95% CI for the RR		(0.978, 1.638)
p-value for RR		0.0734
OR - Odds Ratio (Zuranolone vs. Placebo)		1.799
95% CI for the OR		(0.920, 3.520)
p-value for OR		0.0863
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.134
95% CI for the ARR		(-0.019, 0.287)
p-value for ARR		0.0855

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-ovr.sas:t-cgii-resp12-201-ovr-itta.rtf **Run Date:** 29JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-201B - ITT population

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Study Visit Statistics	Placebo (N=76)	Zuranolone (N =77)
Day 45		
Number of subjects with a response, n (%) [2]	38 (51.4)	52 (68.4)
Number of subjects with missing evaluation, n (%)	6 (8.1)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.322
95% CI for the RR		(1.011, 1.730)
p-value for RR		0.0416
OR - Odds Ratio (Zuranolone vs. Placebo)		1.999
95% CI for the OR		(1.023, 3.907)
p-value for OR		0.0427
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.157
95% CI for the ARR		(0.002, 0.312)
p-value for ARR		0.0464

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure. Relative risk, odds ratio, and absolute risk reduction are estimated from the same GEE model with "Log", "Logit", and "Identity" link function respectively.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-ovr.sas:t-cgii-resp12-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.7.2.1 .2 Subgruppen

4.7.2.1 .2 .1 Interaktionstest

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	74	76	
Number of subjects with response at Day 15, n (%)	38 (51.4)	53 (69.7)	
Number of subjects with response at Day 45, n (%)	38 (51.4)	52 (68.4)	
Age Group (years)			0.8019
Day 15			
18 - 24, n / N (%)	13/25 (52.0)	11/17 (64.7)	
25 - 45, n / N (%)	25/49 (51.0)	42/59 (71.2)	
Day 45			
18 - 24, n / N (%)	11/25 (44.0)	8/17 (47.1)	
25 - 45, n / N (%)	27/49 (55.1)	44/59 (74.6)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved".
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.2092
Day 15			
<28, n / N (%)	12/22 (54.5)	19/30 (63.3)	
>=28, n / N (%)	26/52 (50.0)	34/46 (73.9)	
Day 45			
<28, n / N (%)	14/22 (63.6)	19/30 (63.3)	
>=28, n / N (%)	24/52 (46.2)	33/46 (71.7)	
Race Group (Black or African American, White)			0.1839
Day 15			
Black or African American, n / N (%)	17/31 (54.8)	20/31 (64.5)	
White, n / N (%)	19/40 (47.5)	32/44 (72.7)	
Day 45			
Black or African American, n / N (%)	18/31 (58.1)	20/31 (64.5)	
White, n / N (%)	19/40 (47.5)	31/44 (70.5)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved".
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.4549
Day 15			
Yes, n / N (%)	7/13 (53.8)	13/16 (81.3)	
No, n / N (%)	31/61 (50.8)	40/60 (66.7)	
Day 45			
Yes, n / N (%)	4/13 (30.8)	12/16 (75.0)	
No, n / N (%)	34/61 (55.7)	40/60 (66.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved".
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.2088(a) 0.0832(b) 0.0015(c)
Day 15			
<=24.9, n / N (%)	9/20 (45.0)	9/13 (69.2)	
25-29.9, n / N (%)	7/20 (35.0)	17/21 (81.0)	
>=30, n / N (%)	22/34 (64.7)	27/42 (64.3)	
Day 45			
<=24.9, n / N (%)	8/20 (40.0)	8/13 (61.5)	
25-29.9, n / N (%)	10/20 (50.0)	15/21 (71.4)	
>=30, n / N (%)	20/34 (58.8)	29/42 (69.0)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved".
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.4301
Day 15			
3rd Trimester, n / N (%)	14/31 (45.2)	23/32 (71.9)	
Postpartum, n / N (%)	24/43 (55.8)	30/44 (68.2)	
Day 45			
3rd Trimester, n / N (%)	17/31 (54.8)	24/32 (75.0)	
Postpartum, n / N (%)	21/43 (48.8)	28/44 (63.6)	
Family History of PPD			0.3980
Day 15			
Yes, n / N (%)	4/10 (40.0)	9/10 (90.0)	
No/Unknown, n / N (%)	34/64 (53.1)	44/66 (66.7)	
Day 45			
Yes, n / N (%)	6/10 (60.0)	8/10 (80.0)	
No/Unknown, n / N (%)	32/64 (50.0)	44/66 (66.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved".
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.1991
Day 15			
1st Episode, n / N (%)	33/59 (55.9)	47/66 (71.2)	
Recurrent Episode, n / N (%)	5/15 (33.3)	6/10 (60.0)	
Day 45			
1st Episode, n / N (%)	32/59 (54.2)	46/66 (69.7)	
Recurrent Episode, n / N (%)	6/15 (40.0)	6/10 (60.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	4/8 (50.0)	7/10 (70.0)	
>=20, n / N (%)	34/66 (51.5)	46/66 (69.7)	
Day 45			
<20, n / N (%)	6/8 (75.0)	6/10 (60.0)	
>=20, n / N (%)	32/66 (48.5)	46/66 (69.7)	

NOTE 1: p-value is derived using Method 2, which is the first among the four sequentially evaluated methods to yield an estimate without any warnings or errors. Method 1: Generalized Estimating Equations (GEE) with covariates including antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, subgroup, subgroup-by-treatment interaction, subgroup-by-time point interaction, time point-by-treatment interaction, and subgroup-by-time point-by-treatment interaction with unstructured covariance, "Log" link function, and the binomial distribution. Method 2: Same as Method 1 but with a Poisson distribution. Method 3: Same as Method 2 but excluding the subgroup-by-time point-by-treatment covariate. Method 4: Same as Method 3 but exchangeable covariance structure. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved".
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
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4.7.2.1 .2 .2 Subgruppenanalysen

4.7.2.1 .2 .2 .1 Alter

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Number of evaluable subjects [1]	25	17
Day 3		
Number of subjects with a response, n (%) [2]	7 (28.0)	9 (52.9)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.832
95% CI for the RR		(0.840, 3.997)
p-value for RR		0.1280
Day 8		
Number of subjects with a response, n (%) [2]	13 (52.0)	12 (70.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.338
95% CI for the RR		(0.824, 2.171)
p-value for RR		0.2389

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-age-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 15		
Number of subjects with a response, n (%) [2]	13 (52.0)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.195
95% CI for the RR		(0.702, 2.034)
p-value for RR		0.5126
Day 21		
Number of subjects with a response, n (%) [2]	11 (44.0)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.432
95% CI for the RR		(0.818, 2.509)
p-value for RR		0.2091

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-age-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=26)	Zuranolone (N =18)
Day 45		
Number of subjects with a response, n (%) [2]	11 (44.0)	8 (47.1)
Number of subjects with missing evaluation, n (%)	1 (4.0)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.038
95% CI for the RR		(0.537, 2.007)
p-value for RR		0.9122

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-age-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Number of evaluable subjects [1]	49	59
Day 3		
Number of subjects with a response, n (%) [2]	14 (28.6)	19 (32.2)
Number of subjects with missing evaluation, n (%)	0	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.137
95% CI for the RR		(0.637, 2.030)
p-value for RR		0.6631
Day 8		
Number of subjects with a response, n (%) [2]	24 (49.0)	37 (62.7)
Number of subjects with missing evaluation, n (%)	0	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.291
95% CI for the RR		(0.911, 1.830)
p-value for RR		0.1504

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-age-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 15		
Number of subjects with a response, n (%) [2]	25 (51.0)	42 (71.2)
Number of subjects with missing evaluation, n (%)	1 (2.0)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.410
95% CI for the RR		(1.028, 1.933)
p-value for RR		0.0331
Day 21		
Number of subjects with a response, n (%) [2]	29 (59.2)	41 (69.5)
Number of subjects with missing evaluation, n (%)	1 (2.0)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.192
95% CI for the RR		(0.890, 1.595)
p-value for RR		0.2386

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-age-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=50)	Zuranolone (N =59)
Day 45		
Number of subjects with a response, n (%) [2]	27 (55.1)	44 (74.6)
Number of subjects with missing evaluation, n (%)	5 (10.2)	2 (3.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.377
95% CI for the RR		(1.023, 1.854)
p-value for RR		0.0349

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-age-itta.rtf **Run Date:** 30JUL2025

4.7.2.1 .2 .2 .2 Schwere der Erkrankung

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Number of evaluable subjects [1]	22	30
Day 3		
Number of subjects with a response, n (%) [2]	5 (22.7)	9 (30.0)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.275
95% CI for the RR		(0.501, 3.244)
p-value for RR		0.6105
Day 8		
Number of subjects with a response, n (%) [2]	12 (54.5)	17 (56.7)
Number of subjects with missing evaluation, n (%)	0	1 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.003
95% CI for the RR		(0.618, 1.630)
p-value for RR		0.9895

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-hamd-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 15		
Number of subjects with a response, n (%) [2]	12 (54.5)	19 (63.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.121
95% CI for the RR		(0.710, 1.771)
p-value for RR		0.6236
Day 21		
Number of subjects with a response, n (%) [2]	13 (59.1)	16 (53.3)
Number of subjects with missing evaluation, n (%)	0	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.872
95% CI for the RR		(0.551, 1.379)
p-value for RR		0.5572

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-hamd-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =30)
Day 45		
Number of subjects with a response, n (%) [2]	14 (63.6)	19 (63.3)
Number of subjects with missing evaluation, n (%)	1 (4.5)	2 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.961
95% CI for the RR		(0.652, 1.417)
p-value for RR		0.8413

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-hamd-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Number of evaluable subjects [1]	52	46
Day 3		
Number of subjects with a response, n (%) [2]	16 (30.8)	19 (41.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.331
95% CI for the RR		(0.779, 2.274)
p-value for RR		0.2947
Day 8		
Number of subjects with a response, n (%) [2]	25 (48.1)	32 (69.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.435
95% CI for the RR		(1.020, 2.019)
p-value for RR		0.0379

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-hamd-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 15		
Number of subjects with a response, n (%) [2]	26 (50.0)	34 (73.9)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.466
95% CI for the RR		(1.063, 2.022)
p-value for RR		0.0196
Day 21		
Number of subjects with a response, n (%) [2]	27 (51.9)	36 (78.3)
Number of subjects with missing evaluation, n (%)	1 (1.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.495
95% CI for the RR		(1.104, 2.025)
p-value for RR		0.0094

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-hamd-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Study Visit Statistics	Placebo (N=53)	Zuranolone (N =46)
Day 45		
Number of subjects with a response, n (%) [2]	24 (46.2)	33 (71.7)
Number of subjects with missing evaluation, n (%)	5 (9.6)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.542
95% CI for the RR		(1.092, 2.177)
p-value for RR		0.0140

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-hamd-itta.rtf **Run Date:** 30JUL2025

4.7.2.1 .2 .2 .3 Abstammung

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-201B - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Number of evaluable subjects [1]	31	31
Day 3		
Number of subjects with a response, n (%) [2]	11 (35.5)	10 (32.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.932
95% CI for the RR		(0.478, 1.817)
p-value for RR		0.8360
Day 8		
Number of subjects with a response, n (%) [2]	18 (58.1)	19 (61.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.082
95% CI for the RR		(0.729, 1.607)
p-value for RR		0.6959

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-race-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-201B - ITT population

Page: 2 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 15		
Number of subjects with a response, n (%) [2]	17 (54.8)	20 (64.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.206
95% CI for the RR		(0.807, 1.803)
p-value for RR		0.3611
Day 21		
Number of subjects with a response, n (%) [2]	17 (54.8)	18 (58.1)
Number of subjects with missing evaluation, n (%)	0	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.085
95% CI for the RR		(0.715, 1.647)
p-value for RR		0.7003

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-race-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-201B - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=33)	Zuranolone (N =31)
Day 45		
Number of subjects with a response, n (%) [2]	18 (58.1)	20 (64.5)
Number of subjects with missing evaluation, n (%)	1 (3.2)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.139
95% CI for the RR		(0.772, 1.680)
p-value for RR		0.5117

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-race-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Number of evaluable subjects [1]	40	44
Day 3		
Number of subjects with a response, n (%) [2]	10 (25.0)	17 (38.6)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.534
95% CI for the RR		(0.798, 2.951)
p-value for RR		0.1997
Day 8		
Number of subjects with a response, n (%) [2]	17 (42.5)	29 (65.9)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.540
95% CI for the RR		(1.021, 2.322)
p-value for RR		0.0396

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-race-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	19 (47.5)	32 (72.7)
Number of subjects with missing evaluation, n (%)	1 (2.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.520
95% CI for the RR		(1.051, 2.198)
p-value for RR		0.0261
Day 21		
Number of subjects with a response, n (%) [2]	22 (55.0)	33 (75.0)
Number of subjects with missing evaluation, n (%)	1 (2.5)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.354
95% CI for the RR		(0.973, 1.883)
p-value for RR		0.0718

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-race-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=40)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	19 (47.5)	31 (70.5)
Number of subjects with missing evaluation, n (%)	5 (12.5)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.473
95% CI for the RR		(1.004, 2.159)
p-value for RR		0.0475

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-race-itta.rtf **Run Date:** 30JUL2025

4.7.2.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 1 of 6

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Number of evaluable subjects [1]	13	16
Day 3		
Number of subjects with a response, n (%) [2]	3 (23.1)	5 (31.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.352
95% CI for the RR		(0.395, 4.633)
p-value for RR		0.6308
Day 8		
Number of subjects with a response, n (%) [2]	7 (53.8)	11 (68.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.276
95% CI for the RR		(0.702, 2.319)
p-value for RR		0.4247

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-adt-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 15		
Number of subjects with a response, n (%) [2]	7 (53.8)	13 (81.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.502
95% CI for the RR		(0.866, 2.605)
p-value for RR		0.1481
Day 21		
Number of subjects with a response, n (%) [2]	6 (46.2)	12 (75.0)
Number of subjects with missing evaluation, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.628
95% CI for the RR		(0.849, 3.122)
p-value for RR		0.1424

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-adt-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Page: 3 of 6

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =16)
Day 45		
Number of subjects with a response, n (%) [2]	4 (30.8)	12 (75.0)
Number of subjects with missing evaluation, n (%)	3 (23.1)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.442
95% CI for the RR		(1.034, 5.768)
p-value for RR		0.0417

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-adt-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Number of evaluable subjects [1]	61	60
Day 3		
Number of subjects with a response, n (%) [2]	18 (29.5)	23 (38.3)
Number of subjects with missing evaluation, n (%)	0	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.299
95% CI for the RR		(0.787, 2.144)
p-value for RR		0.3058
Day 8		
Number of subjects with a response, n (%) [2]	30 (49.2)	38 (63.3)
Number of subjects with missing evaluation, n (%)	0	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.296
95% CI for the RR		(0.943, 1.781)
p-value for RR		0.1094

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-adt-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 15		
Number of subjects with a response, n (%) [2]	31 (50.8)	40 (66.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.319
95% CI for the RR		(0.973, 1.788)
p-value for RR		0.0747
Day 21		
Number of subjects with a response, n (%) [2]	34 (55.7)	40 (66.7)
Number of subjects with missing evaluation, n (%)	0	1 (1.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.192
95% CI for the RR		(0.897, 1.585)
p-value for RR		0.2255

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-adt-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=63)	Zuranolone (N =61)
Day 45		
Number of subjects with a response, n (%) [2]	34 (55.7)	40 (66.7)
Number of subjects with missing evaluation, n (%)	3 (4.9)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.179
95% CI for the RR		(0.886, 1.568)
p-value for RR		0.2584

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-adt-itta.rtf **Run Date:** 30JUL2025

4.7.2.1 .2 .2 .5 BMI

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Number of evaluable subjects [1]	20	13
Day 3		
Number of subjects with a response, n (%) [2]	6 (30.0)	6 (46.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.542
95% CI for the RR		(0.682, 3.485)
p-value for RR		0.2977
Day 8		
Number of subjects with a response, n (%) [2]	9 (45.0)	8 (61.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.371
95% CI for the RR		(0.753, 2.494)
p-value for RR		0.3019

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-bmi-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 15		
Number of subjects with a response, n (%) [2]	9 (45.0)	9 (69.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.542
95% CI for the RR		(0.851, 2.795)
p-value for RR		0.1535
Day 21		
Number of subjects with a response, n (%) [2]	8 (40.0)	9 (69.2)
Number of subjects with missing evaluation, n (%)	1 (5.0)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.735
95% CI for the RR		(0.946, 3.183)
p-value for RR		0.0752

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-bmi-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = <=24.9

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =13)
Day 45		
Number of subjects with a response, n (%) [2]	8 (40.0)	8 (61.5)
Number of subjects with missing evaluation, n (%)	2 (10.0)	1 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.542
95% CI for the RR		(0.802, 2.964)
p-value for RR		0.1939

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-bmi-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Number of evaluable subjects [1]	20	21
Day 3		
Number of subjects with a response, n (%) [2]	1 (5.0)	10 (47.6)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		9.467
95% CI for the RR		(1.322, 67.785)
p-value for RR		0.0252
Day 8		
Number of subjects with a response, n (%) [2]	8 (40.0)	16 (76.2)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.893
95% CI for the RR		(1.056, 3.395)
p-value for RR		0.0321

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-bmi-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	7 (35.0)	17 (81.0)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.299
95% CI for the RR		(1.219, 4.338)
p-value for RR		0.0102
Day 21		
Number of subjects with a response, n (%) [2]	9 (45.0)	15 (71.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.578
95% CI for the RR		(0.900, 2.767)
p-value for RR		0.1115

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-bmi-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = 25-29.9

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =21)
Day 45		
Number of subjects with a response, n (%) [2]	10 (50.0)	15 (71.4)
Number of subjects with missing evaluation, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.420
95% CI for the RR		(0.850, 2.371)
p-value for RR		0.1801

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-bmi-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Number of evaluable subjects [1]	34	42
Day 3		
Number of subjects with a response, n (%) [2]	14 (41.2)	12 (28.6)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.692
95% CI for the RR		(0.368, 1.303)
p-value for RR		0.2542
Day 8		
Number of subjects with a response, n (%) [2]	20 (58.8)	25 (59.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.010
95% CI for the RR		(0.694, 1.469)
p-value for RR		0.9593

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-bmi-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 15		
Number of subjects with a response, n (%) [2]	22 (64.7)	27 (64.3)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.991
95% CI for the RR		(0.710, 1.384)
p-value for RR		0.9598
Day 21		
Number of subjects with a response, n (%) [2]	23 (67.6)	28 (66.7)
Number of subjects with missing evaluation, n (%)	0	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.983
95% CI for the RR		(0.717, 1.350)
p-value for RR		0.9178

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-bmi-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m2) Group 2 = >=30

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =42)
Day 45		
Number of subjects with a response, n (%) [2]	20 (58.8)	29 (69.0)
Number of subjects with missing evaluation, n (%)	4 (11.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.171
95% CI for the RR		(0.823, 1.667)
p-value for RR		0.3794

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-bmi-itta.rtf **Run Date:** 30JUL2025

4.7.2.1 .2 .2 .6 Beginn der PPD

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Number of evaluable subjects [1]	31	32
Day 3		
Number of subjects with a response, n (%) [2]	9 (29.0)	16 (50.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.708
95% CI for the RR		(0.886, 3.292)
p-value for RR		0.1100
Day 8		
Number of subjects with a response, n (%) [2]	16 (51.6)	23 (71.9)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.381
95% CI for the RR		(0.918, 2.078)
p-value for RR		0.1217

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-onset-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 15		
Number of subjects with a response, n (%) [2]	14 (45.2)	23 (71.9)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.578
95% CI for the RR		(1.008, 2.471)
p-value for RR		0.0461
Day 21		
Number of subjects with a response, n (%) [2]	18 (58.1)	22 (68.8)
Number of subjects with missing evaluation, n (%)	1 (3.2)	1 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.174
95% CI for the RR		(0.801, 1.721)
p-value for RR		0.4107

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-onset-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =32)
Day 45		
Number of subjects with a response, n (%) [2]	17 (54.8)	24 (75.0)
Number of subjects with missing evaluation, n (%)	2 (6.5)	2 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.356
95% CI for the RR		(0.927, 1.984)
p-value for RR		0.1164

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-onset-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Number of evaluable subjects [1]	43	44
Day 3		
Number of subjects with a response, n (%) [2]	12 (27.9)	12 (27.3)
Number of subjects with missing evaluation, n (%)	0	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.969
95% CI for the RR		(0.490, 1.916)
p-value for RR		0.9286
Day 8		
Number of subjects with a response, n (%) [2]	21 (48.8)	26 (59.1)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.200
95% CI for the RR		(0.809, 1.780)
p-value for RR		0.3646

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-onset-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 15		
Number of subjects with a response, n (%) [2]	24 (55.8)	30 (68.2)
Number of subjects with missing evaluation, n (%)	1 (2.3)	2 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.212
95% CI for the RR		(0.866, 1.696)
p-value for RR		0.2632
Day 21		
Number of subjects with a response, n (%) [2]	22 (51.2)	30 (68.2)
Number of subjects with missing evaluation, n (%)	0	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.322
95% CI for the RR		(0.925, 1.890)
p-value for RR		0.1261

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-onset-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=44)	Zuranolone (N =45)
Day 45		
Number of subjects with a response, n (%) [2]	21 (48.8)	28 (63.6)
Number of subjects with missing evaluation, n (%)	4 (9.3)	1 (2.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.292
95% CI for the RR		(0.883, 1.892)
p-value for RR		0.1874

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with unstructured covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-onset-itta.rtf **Run Date:** 30JUL2025

4.7.2.1 .2 .2 .7 PPD in der Familie

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-201B - ITT population

Page: 1 of 6

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Number of evaluable subjects [1]	10	10
Day 3		
Number of subjects with a response, n (%) [2]	2 (20.0)	2 (20.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.192
95% CI for the RR		(0.210, 6.782)
p-value for RR		0.8426
Day 8		
Number of subjects with a response, n (%) [2]	4 (40.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.087
95% CI for the RR		(0.849, 5.128)
p-value for RR		0.1088

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-fhist-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	4 (40.0)	9 (90.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.683
95% CI for the RR		(1.242, 5.797)
p-value for RR		0.0120
Day 21		
Number of subjects with a response, n (%) [2]	6 (60.0)	9 (90.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.789
95% CI for the RR		(1.064, 3.007)
p-value for RR		0.0282

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-fhist-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=10)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	6 (60.0)	8 (80.0)
Number of subjects with missing evaluation, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.590
95% CI for the RR		(0.960, 2.633)
p-value for RR		0.0716

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-fhist-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Number of evaluable subjects [1]	64	66
Day 3		
Number of subjects with a response, n (%) [2]	19 (29.7)	26 (39.4)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.312
95% CI for the RR		(0.808, 2.130)
p-value for RR		0.2720
Day 8		
Number of subjects with a response, n (%) [2]	33 (51.6)	42 (63.6)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.220
95% CI for the RR		(0.904, 1.647)
p-value for RR		0.1934

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-fhist-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	34 (53.1)	44 (66.7)
Number of subjects with missing evaluation, n (%)	1 (1.6)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.241
95% CI for the RR		(0.929, 1.657)
p-value for RR		0.1441
Day 21		
Number of subjects with a response, n (%) [2]	34 (53.1)	43 (65.2)
Number of subjects with missing evaluation, n (%)	1 (1.6)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.213
95% CI for the RR		(0.906, 1.624)
p-value for RR		0.1957

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-fhist-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	32 (50.0)	44 (66.7)
Number of subjects with missing evaluation, n (%)	5 (7.8)	3 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.318
95% CI for the RR		(0.976, 1.781)
p-value for RR		0.0715

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-fhist-itta.rtf **Run Date:** 30JUL2025

4.7.2.1 .2 .2 .8 PPD in der Anamnese

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Number of evaluable subjects [1]	59	66
Day 3		
Number of subjects with a response, n (%) [2]	19 (32.2)	23 (34.8)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.071
95% CI for the RR		(0.654, 1.754)
p-value for RR		0.7840
Day 8		
Number of subjects with a response, n (%) [2]	31 (52.5)	43 (65.2)
Number of subjects with missing evaluation, n (%)	0	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.228
95% CI for the RR		(0.910, 1.657)
p-value for RR		0.1800

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-hist-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 6

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 15		
Number of subjects with a response, n (%) [2]	33 (55.9)	47 (71.2)
Number of subjects with missing evaluation, n (%)	0	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.260
95% CI for the RR		(0.958, 1.658)
p-value for RR		0.0981
Day 21		
Number of subjects with a response, n (%) [2]	34 (57.6)	45 (68.2)
Number of subjects with missing evaluation, n (%)	1 (1.7)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.171
95% CI for the RR		(0.892, 1.539)
p-value for RR		0.2560

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-hist-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=60)	Zuranolone (N =67)
Day 45		
Number of subjects with a response, n (%) [2]	32 (54.2)	46 (69.7)
Number of subjects with missing evaluation, n (%)	5 (8.5)	2 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.272
95% CI for the RR		(0.960, 1.686)
p-value for RR		0.0939

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-hist-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Number of evaluable subjects [1]	15	10
Day 3		
Number of subjects with a response, n (%) [2]	2 (13.3)	5 (50.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.560
95% CI for the RR		(0.816, 15.532)
p-value for RR		0.0912
Day 8		
Number of subjects with a response, n (%) [2]	6 (40.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.424
95% CI for the RR		(0.633, 3.204)
p-value for RR		0.3932

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-hist-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 15		
Number of subjects with a response, n (%) [2]	5 (33.3)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.709
95% CI for the RR		(0.714, 4.087)
p-value for RR		0.2286
Day 21		
Number of subjects with a response, n (%) [2]	6 (40.0)	7 (70.0)
Number of subjects with missing evaluation, n (%)	0	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.661
95% CI for the RR		(0.785, 3.517)
p-value for RR		0.1848

NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-hist-itta.rtf **Run Date:** 30JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =10)
Day 45		
Number of subjects with a response, n (%) [2]	6 (40.0)	6 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.7)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.424
95% CI for the RR		(0.637, 3.181)
p-value for RR		0.3890

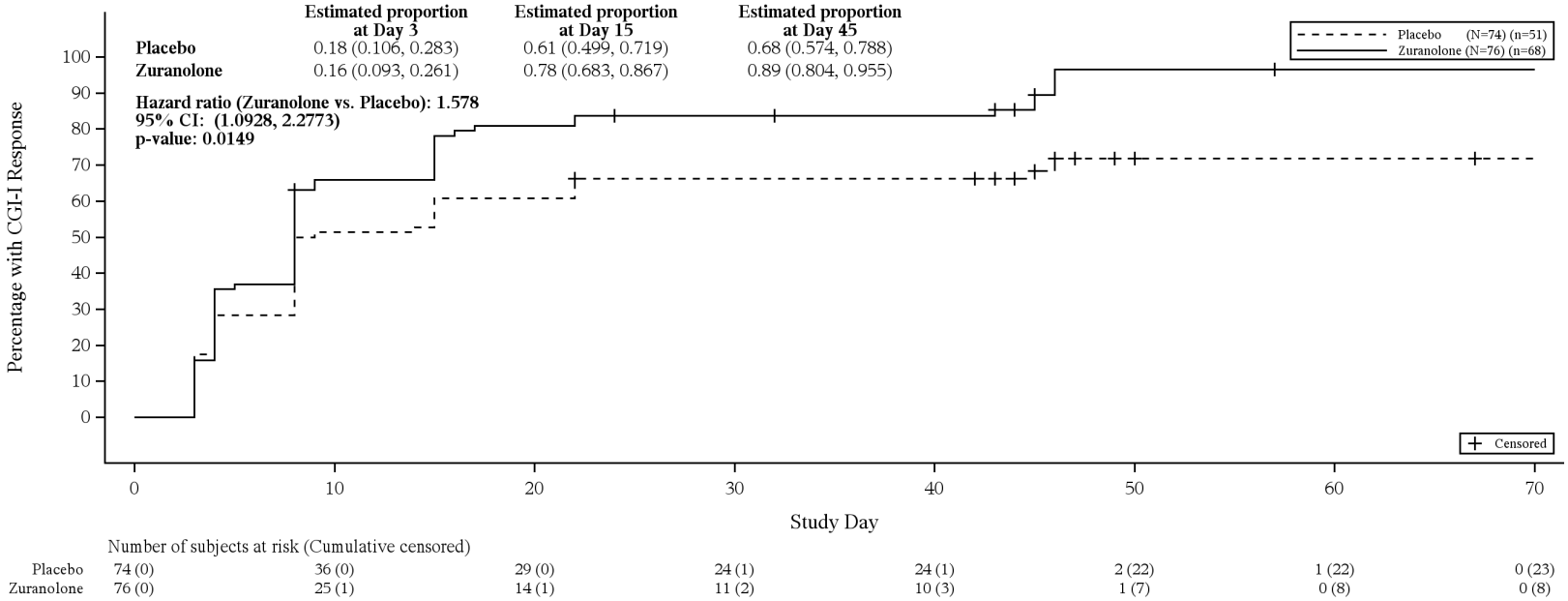
NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson distribution.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response ("much improved" or "very much improved"). Missing score at the visit has been imputed as "no response". The denominator for the percentage is the number of evaluable subjects.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-201-by.sas:t-cgii-resp12-201-by-hist-itta.rtf **Run Date:** 30JUL2025

4.7.2.2 TTE-Analysen

4.7.2.2 .1 ITT-Population

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-201B - ITT population

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Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing CGI-I score at any visit.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment.
Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-ovr.sas:f-cgii-resp12-tte-201-ovr-itta.rtf **Run Date:** 15DEC2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-201B - ITT population

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	Placebo (N=76)	Zuranolone (N=77)
Number of evaluable subjects [1]	74	76
Number of subjects with response, n (%) [2]	51 (68.9)	68 (89.5)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.5 (8.0 , 22.0)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	15.0 (9.0 , 43.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.578
95% CI for the HR		(1.0928 , 2.2773)
p-value for the HR		0.0149

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
[1] Number of subjects with non-missing CGI-I score at any visit.
[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.
[3] Kaplan-Meier estimates. NE=not estimable.
[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-ovr.sas:t-cgii-resp12-tte-201-ovr-itta.rtf **Run Date:** 29JUL2025

4.7.2.2 .2 Subgruppen

4.7.2.2 .2 .1 Interaktionstest

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	74	76	
Number of subjects with response, n (%)	51 (68.9)	68 (89.5)	
Age Group (years)			
18 - 24, n / N (%)	16/25 (64.0)	16/17 (94.1)	0.3035
25 - 45, n / N (%)	35/49 (71.4)	52/59 (88.1)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	18/22 (81.8)	25/30 (83.3)	0.0967
>=28, n / N (%)	33/52 (63.5)	43/46 (93.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	22/31 (71.0)	28/31 (90.3)	0.3549
White, n / N (%)	27/40 (67.5)	39/44 (88.6)	
Antidepressant Use at Baseline			
Yes, n / N (%)	9/13 (69.2)	15/16 (93.8)	0.8228
No, n / N (%)	42/61 (68.9)	53/60 (88.3)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-int.sas:t-cgii-resp12-tte-201-int-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-201B - ITT population

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Subgroup Subgroup Category	Placebo (N=76)	Zuranolone (N=77)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	12/20 (60.0)	12/13 (92.3)	0.7699(a)
25-29.9, n / N (%)	13/20 (65.0)	19/21 (90.5)	0.1064(b)
>=30, n / N (%)	26/34 (76.5)	37/42 (88.1)	0.0349(c)
Onset of PPD			
3rd Trimester, n / N (%)	23/31 (74.2)	30/32 (93.8)	0.7331
Postpartum, n / N (%)	28/43 (65.1)	38/44 (86.4)	
Family History of PPD			
Yes, n / N (%)	8/10 (80.0)	10/10 (100.0)	0.8209
No/Unknown, n / N (%)	43/64 (67.2)	58/66 (87.9)	
History of PPD			
1st Episode, n / N (%)	44/59 (74.6)	59/66 (89.4)	0.1214
Recurrent Episode, n / N (%)	7/15 (46.7)	9/10 (90.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	6/8 (75.0)	9/10 (90.0)	NA
>=20, n / N (%)	45/66 (68.2)	59/66 (89.4)	

NOTE 1: p-value is based on the Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, treatment, subgroup, and subgroup-by-treatment interaction. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: n / N (%) = number of evaluable subjects with response in the subgroup / number of evaluable subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-int.sas:t-cgii-resp12-tte-201-int-itta.rtf **Run Date:** 29JUL2025

4.7.2.2 .2 .2 Subgruppenanalysen

4.7.2.2 .2 .2 .1 Alter

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-201B - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=26)	Zuranolone (N=18)
Number of evaluable subjects [1]	25	17
Number of subjects with response, n (%) [2]	16 (64.0)	16 (94.1)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	9.0 (8.0, NE)	5.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (15.0, NE)	15.0 (5.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.007
95% CI for the HR		(0.9894 , 4.0709)
p-value for the HR		0.0535

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-201B - ITT population

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Age Group (years) = 25-45

	Placebo (N=50)	Zuranolone (N=59)
Number of evaluable subjects [1]	49	59
Number of subjects with response, n (%) [2]	35 (71.4)	52 (88.1)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 22.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	46.0 (22.0, NE)	15.0 (9.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.440
95% CI for the HR		(0.9344 , 2.2184)
p-value for the HR		0.0985

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-age-itta.rtf **Run Date:** 29JUL2025

4.7.2.2 .2 .2 .2 Schwere der Erkrankung

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=22)	Zuranolone (N=30)
Number of evaluable subjects [1]	22	30
Number of subjects with response, n (%) [2]	18 (81.8)	25 (83.3)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.5 (8.0 , 22.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	22.0 (9.0, NE)	43.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.037
95% CI for the HR		(0.5588 , 1.9260)
p-value for the HR		0.9073

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=53)	Zuranolone (N=46)
Number of evaluable subjects [1]	52	46
Number of subjects with response, n (%) [2]	33 (63.5)	43 (93.5)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	11.0 (8.0 , 45.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	15.0 (8.0 , 17.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.869
95% CI for the HR		(1.1787 , 2.9625)
p-value for the HR		0.0078

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-hamd-itta.rtf **Run Date:** 29JUL2025

4.7.2.2 .2 .2 .3 Abstammung

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-201B - ITT population

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Race Group = Black or African American

	Placebo (N=33)	Zuranolone (N=31)
Number of evaluable subjects [1]	31	31
Number of subjects with response, n (%) [2]	22 (71.0)	28 (90.3)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (4.0 , 15.0)	8.0 (5.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (8.0, NE)	22.0 (9.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.276
95% CI for the HR		(0.7283 , 2.2338)
p-value for the HR		0.3947

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-201B - ITT population

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Race Group = White

	Placebo (N=40)	Zuranolone (N=45)
Number of evaluable subjects [1]	40	44
Number of subjects with response, n (%) [2]	27 (67.5)	39 (88.6)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	6.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0 , 45.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	15.0 (8.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.841
95% CI for the HR		(1.1074 , 3.0597)
p-value for the HR		0.0186

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-race-itta.rtf **Run Date:** 29JUL2025

4.7.2.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of evaluable subjects [1]	13	16
Number of subjects with response, n (%) [2]	9 (69.2)	15 (93.8)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	9.0 (4.0, NE)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (8.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.726
95% CI for the HR		(0.7469 , 3.9904)
p-value for the HR		0.2015

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=63)	Zuranolone (N=61)
Number of evaluable subjects [1]	61	60
Number of subjects with response, n (%) [2]	42 (68.9)	53 (88.3)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 22.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	15.5 (9.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.531
95% CI for the HR		(1.0172 , 2.3028)
p-value for the HR		0.0412

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-adt-itta.rtf **Run Date:** 29JUL2025

4.7.2.2 .2 .2 .5 BMI

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=21)	Zuranolone (N=13)
Number of evaluable subjects [1]	20	13
Number of subjects with response, n (%) [2]	12 (60.0)	12 (92.3)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (4.0, NE)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	15.0 (4.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.273
95% CI for the HR		(0.9937 , 5.2013)
p-value for the HR		0.0518

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=20)	Zuranolone (N=21)
Number of evaluable subjects [1]	20	21
Number of subjects with response, n (%) [2]	13 (65.0)	19 (90.5)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 15.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	22.0 (8.0, NE)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	9.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.851
95% CI for the HR		(1.3277 , 6.1215)
p-value for the HR		0.0072

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of evaluable subjects [1]	34	42
Number of subjects with response, n (%) [2]	26 (76.5)	37 (88.1)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 4.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (4.0 , 15.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	15.0 (8.0, NE)	22.0 (8.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.041
95% CI for the HR		(0.6275 , 1.7279)
p-value for the HR		0.8755

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-bmi-itta.rtf **Run Date:** 29JUL2025

4.7.2.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=32)
Number of evaluable subjects [1]	31	32
Number of subjects with response, n (%) [2]	23 (74.2)	30 (93.8)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 22.0)	6.5 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	45.0 (15.0, NE)	12.0 (8.0 , 43.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.737
95% CI for the HR		(0.9988 , 3.0194)
p-value for the HR		0.0505

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-201B - ITT population

Onset of PPD = Postpartum

	Placebo (N=44)	Zuranolone (N=45)
Number of evaluable subjects [1]	43	44
Number of subjects with response, n (%) [2]	28 (65.1)	38 (86.4)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (4.0 , 8.0)
50th percentile - median (95% CI)	14.0 (8.0 , 46.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	16.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.512
95% CI for the HR		(0.9207 , 2.4840)
p-value for the HR		0.1024

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-onset-itta.rtf **Run Date:** 29JUL2025

4.7.2.2 .2 .2 .7 PPD in der Familie

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of evaluable subjects [1]	10	10
Number of subjects with response, n (%) [2]	8 (80.0)	10 (100.0)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 15.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	11.5 (3.0, NE)	8.0 (3.0 , 8.0)
75th percentile - Q3 (95% CI)	46.0 (8.0, NE)	8.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.286
95% CI for the HR		(0.7401 , 7.0623)
p-value for the HR		0.1508

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=66)	Zuranolone (N=67)
Number of evaluable subjects [1]	64	66
Number of subjects with response, n (%) [2]	43 (67.2)	58 (87.9)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.5 (8.0 , 22.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	NE (22.0, NE)	16.0 (9.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.555
95% CI for the HR		(1.0430 , 2.3171)
p-value for the HR		0.0302

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-fhist-itta.rtf **Run Date:** 29JUL2025

4.7.2.2 .2 .2 .8 PPD in der Anamnese

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-201B - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=60)	Zuranolone (N=67)
Number of evaluable subjects [1]	59	66
Number of subjects with response, n (%) [2]	44 (74.6)	59 (89.4)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	46.0 (15.0, NE)	15.0 (9.0 , 45.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.385
95% CI for the HR		(0.9336 , 2.0560)
p-value for the HR		0.1054

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-201B - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of evaluable subjects [1]	15	10
Number of subjects with response, n (%) [2]	7 (46.7)	9 (90.0)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 15.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	NE (8.0, NE)	6.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	15.0 (4.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.776
95% CI for the HR		(0.9479 , 8.1288)
p-value for the HR		0.0625

NOTE 1: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

[1] Number of subjects with non-missing CGI-I score at any visit.

[2] Number of subjects with a CGI-I response. The denominator for the percentage is the number of evaluable subjects.

[3] Kaplan-Meier estimates. NE=not estimable.

[4] From Cox proportional hazards model with factors for antidepressant use at baseline, baseline CGI-S score, and treatment.

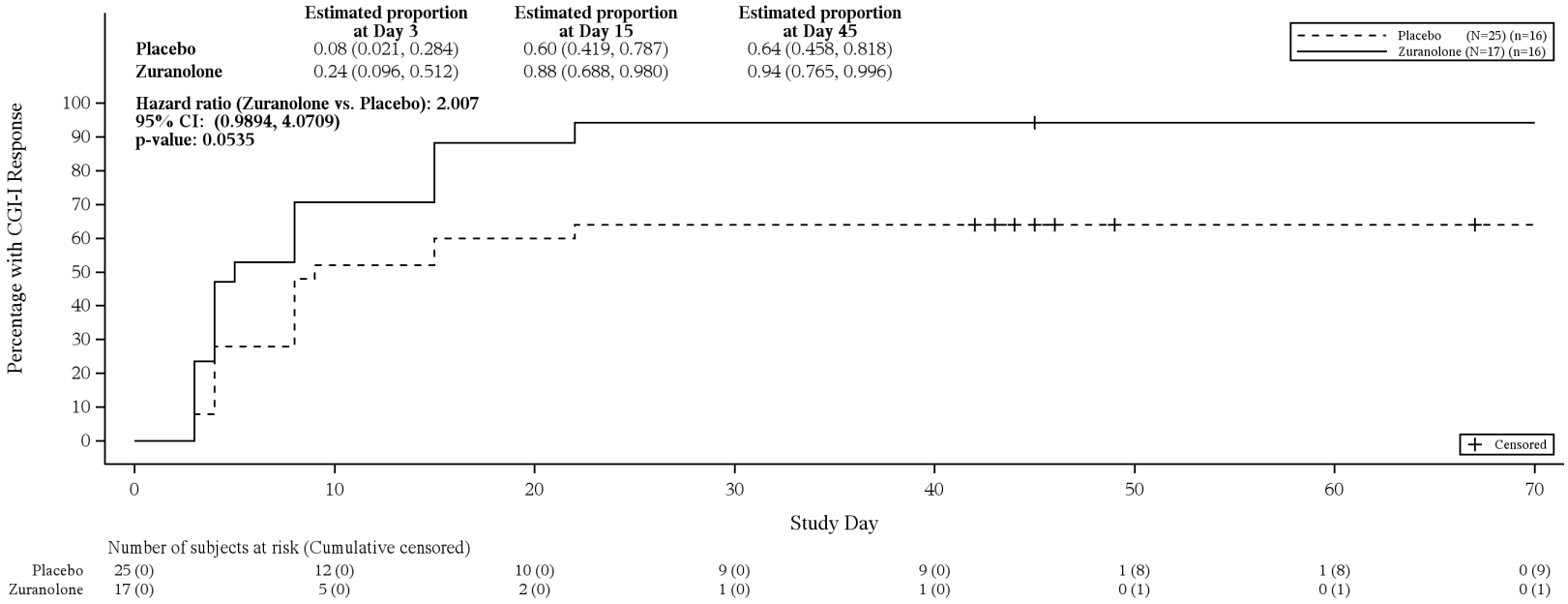
Source: biib125/v_a/germany_amnog/t-cgii-resp12-tte-201-by.sas:t-cgii-resp12-tte-201-by-hist-itta.rtf **Run Date:** 29JUL2025

4.7.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

Page: 1 of 17

Age Group (years) = 18-24

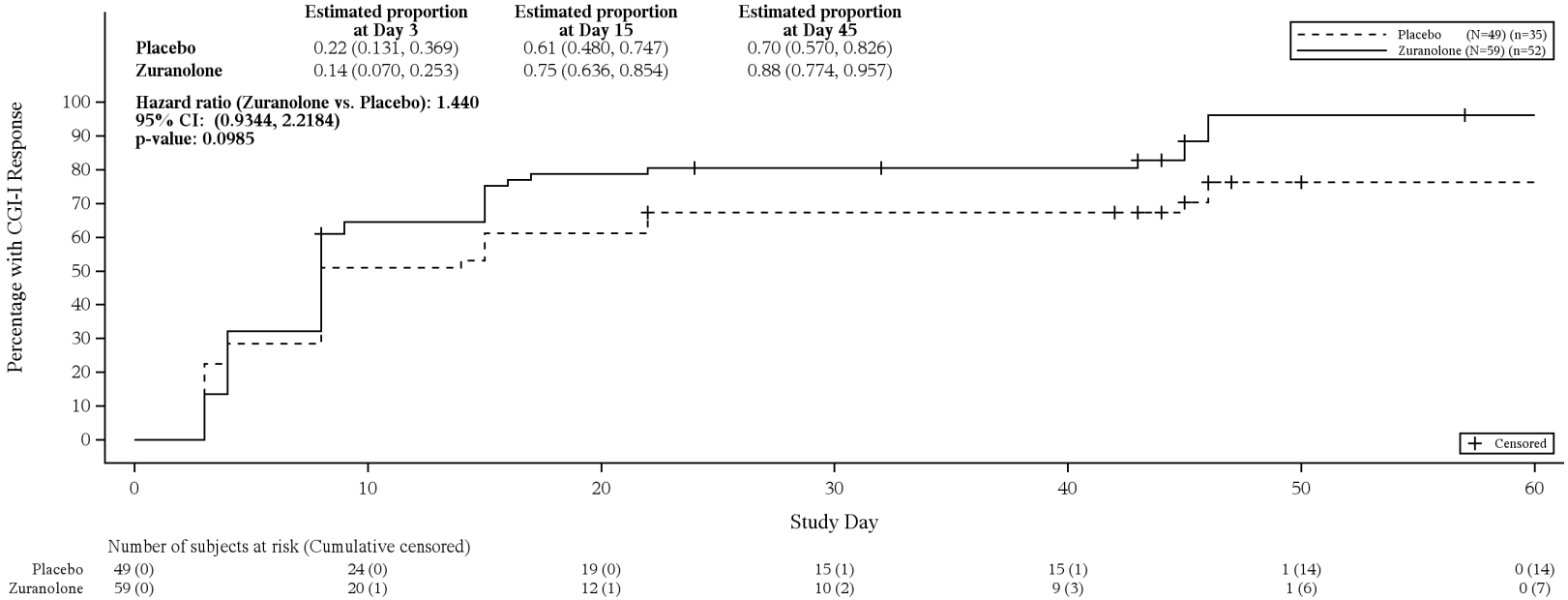


Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing CGI-I score at any visit.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.
Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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Age Group (years) = 25-45



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

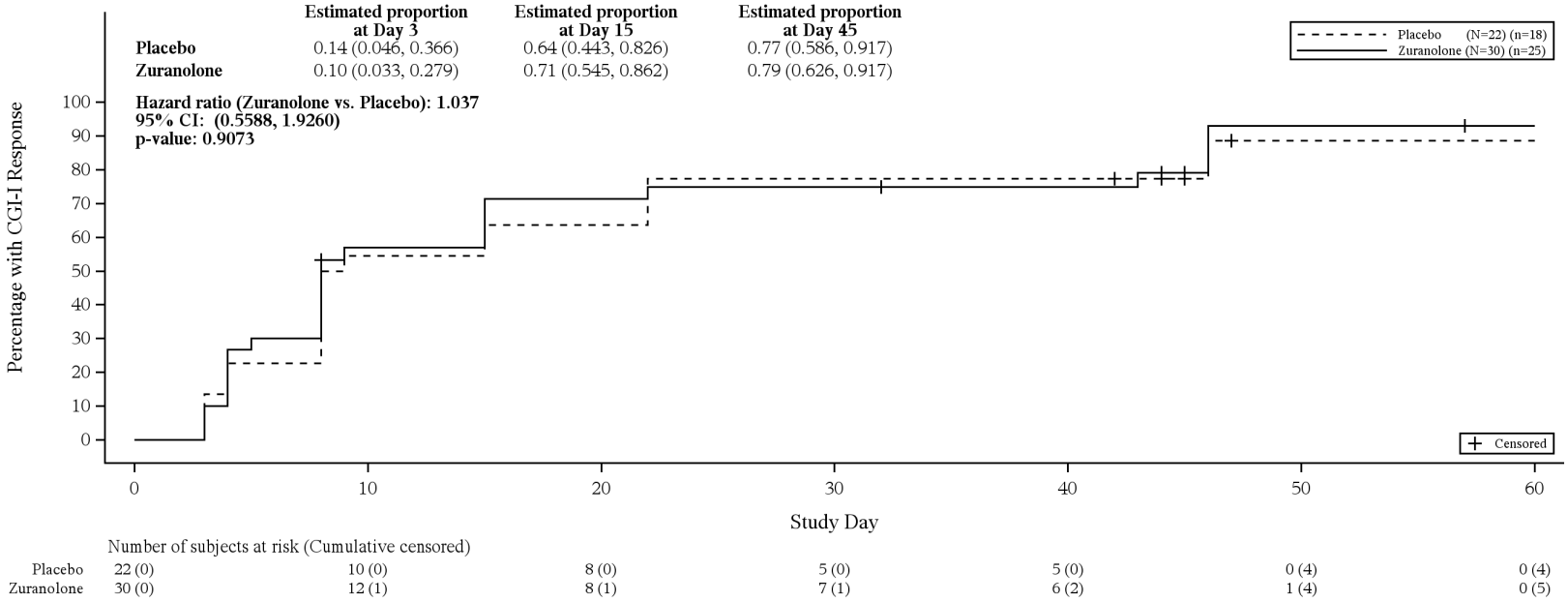
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

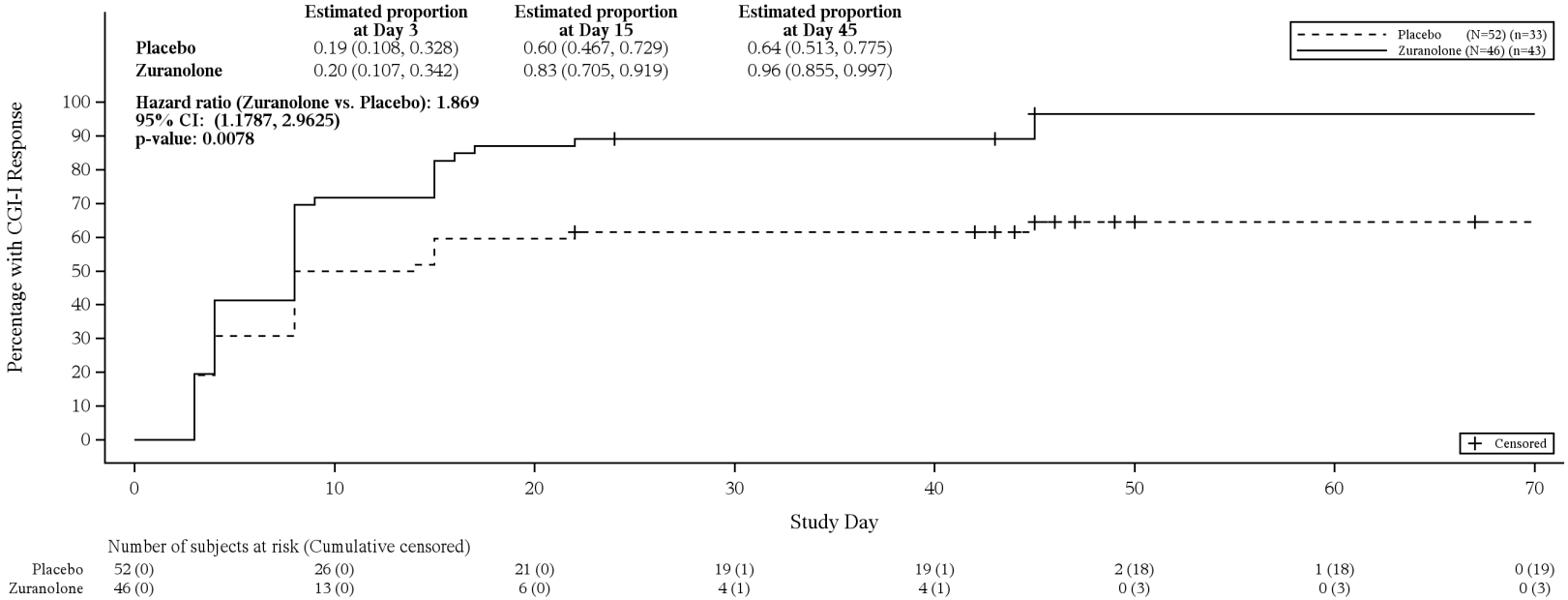
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

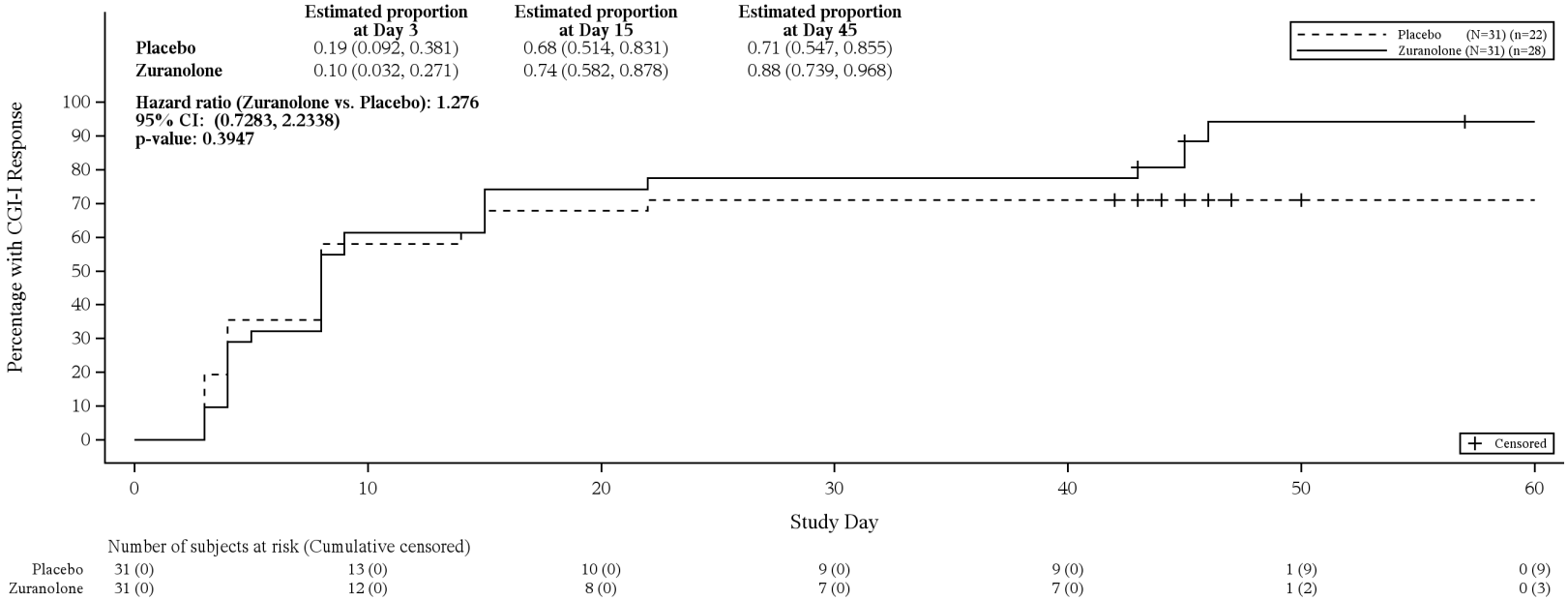
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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Race Group = Black or African American



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

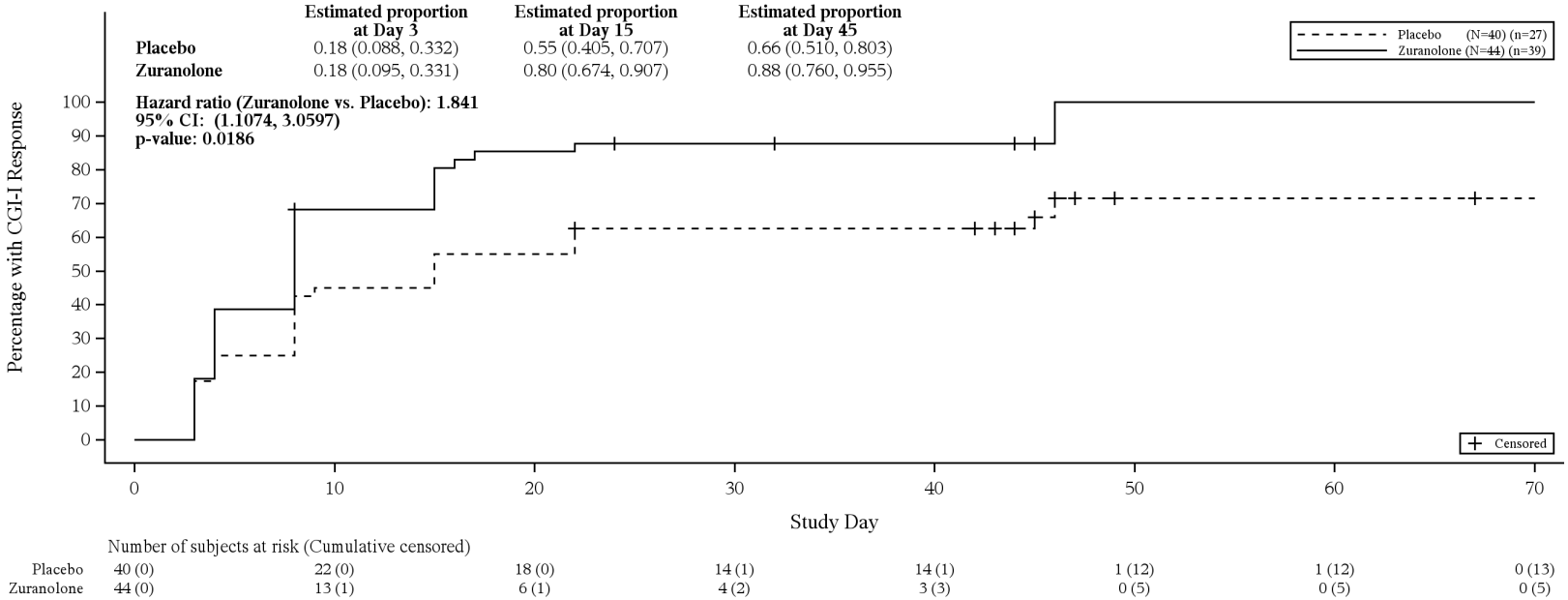
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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Race Group = White



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

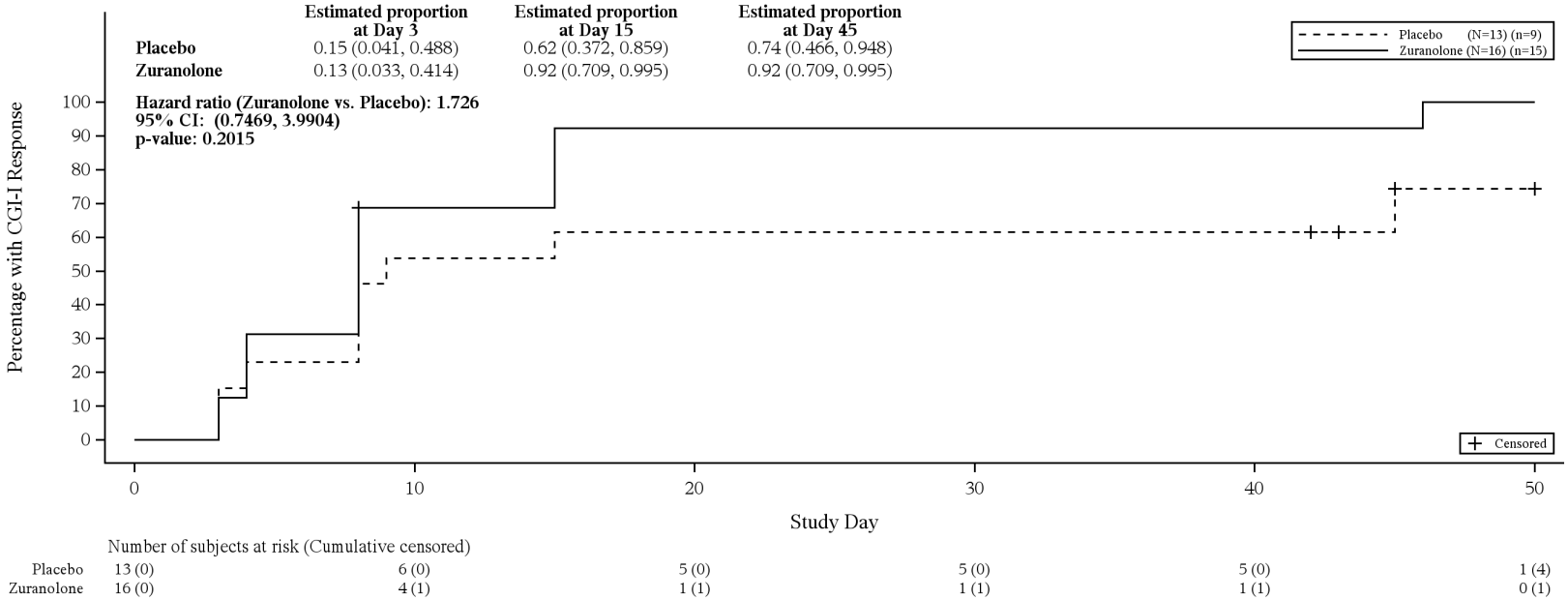
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Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

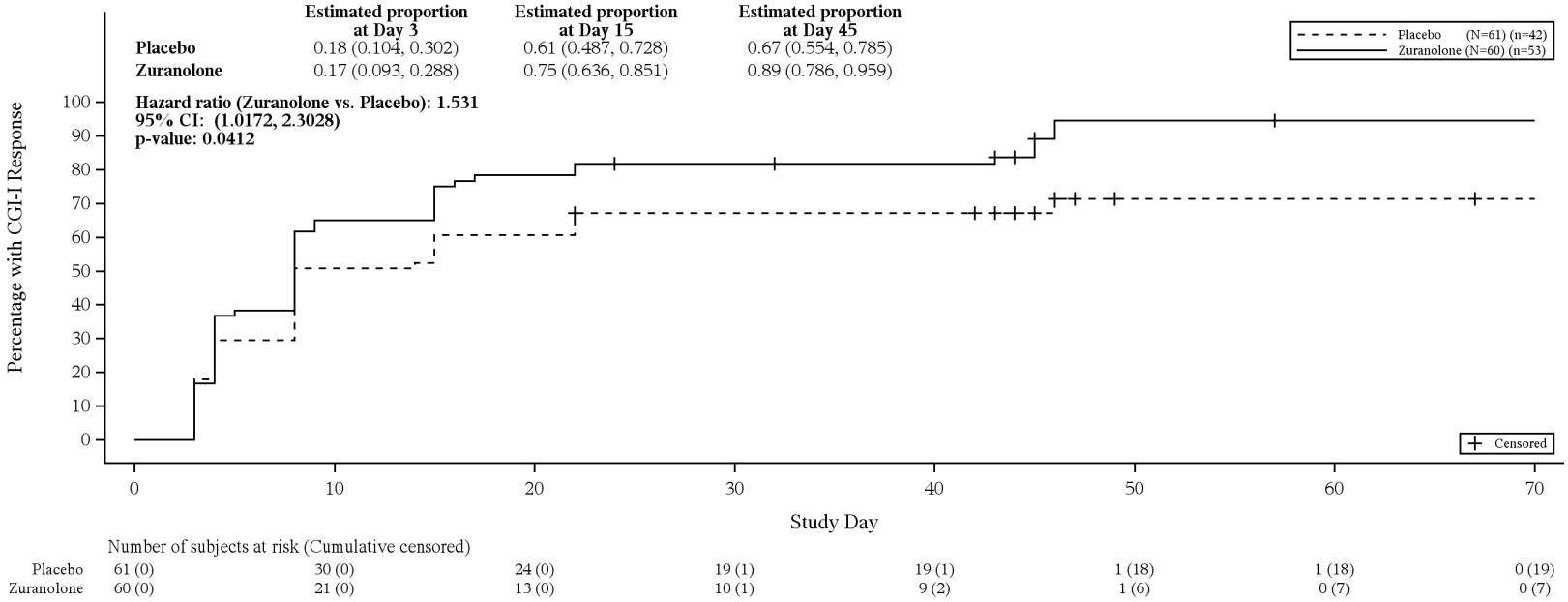
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

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Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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Antidepressant Use at Baseline = No



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

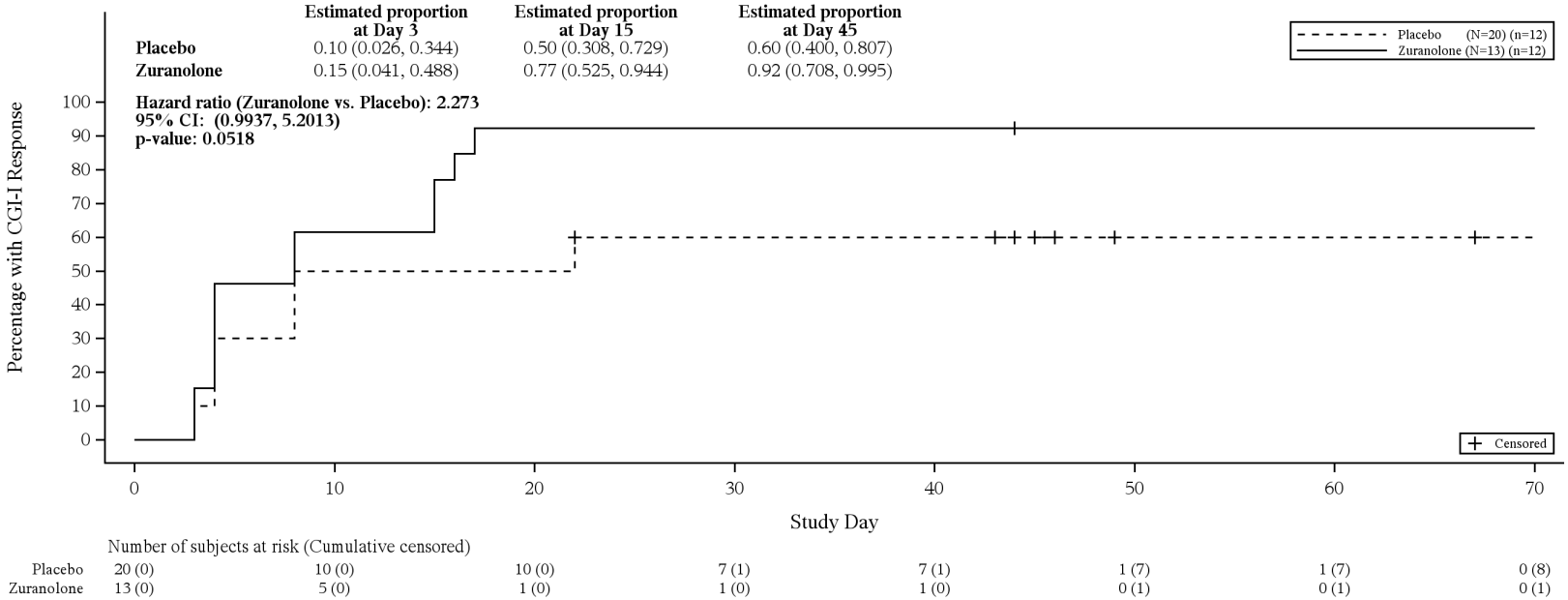
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Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = <=24.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

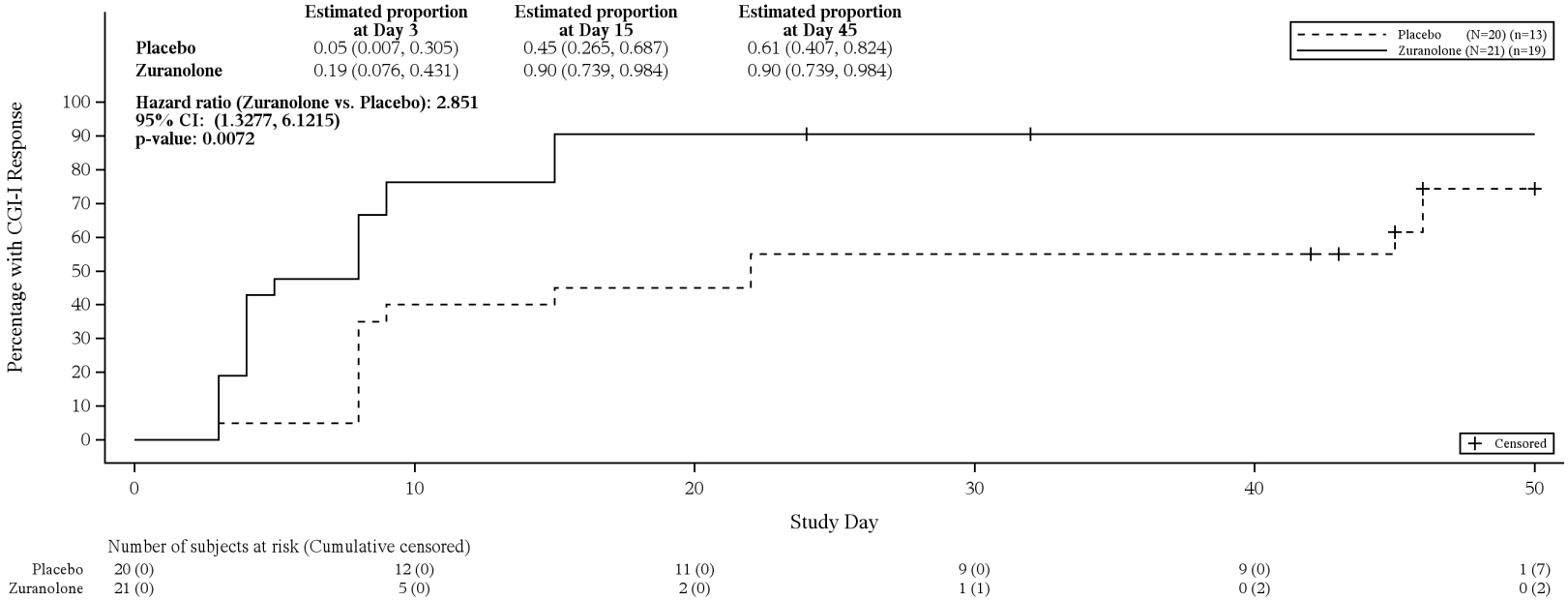
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = 25-29.9



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

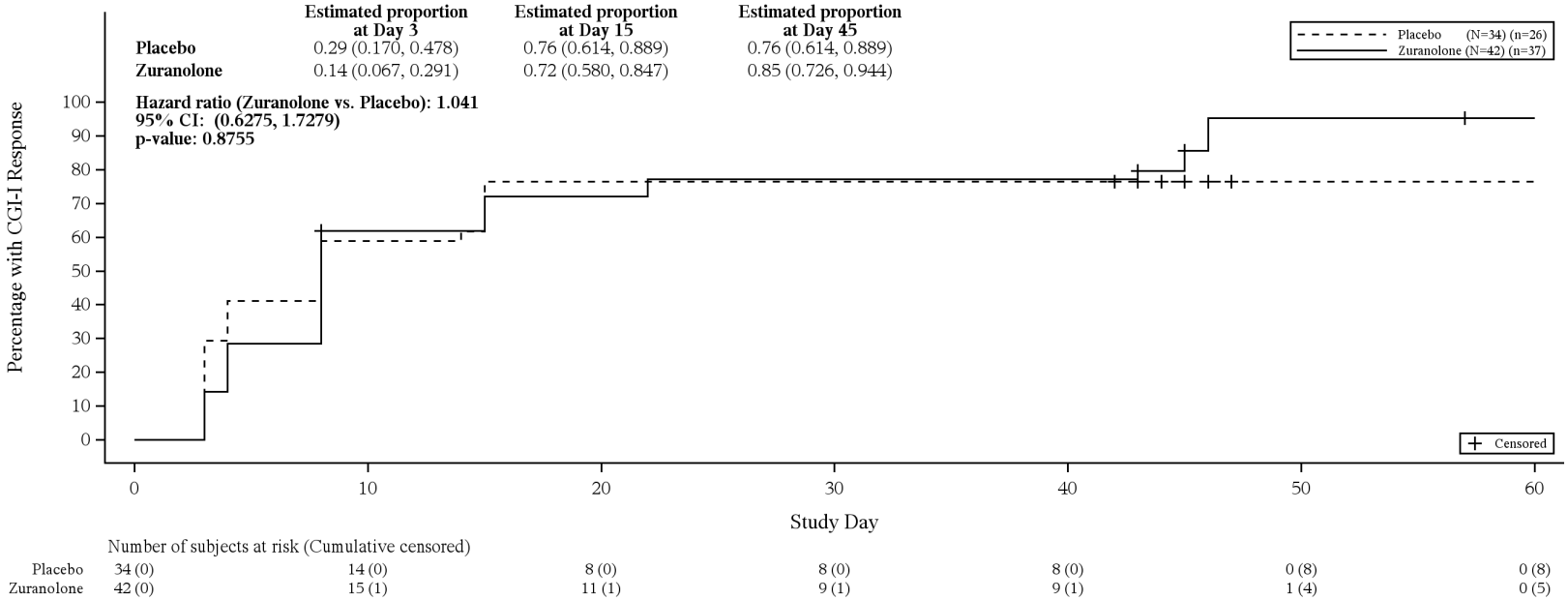
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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BMI (kg/m^2) Group 2 = >=30



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

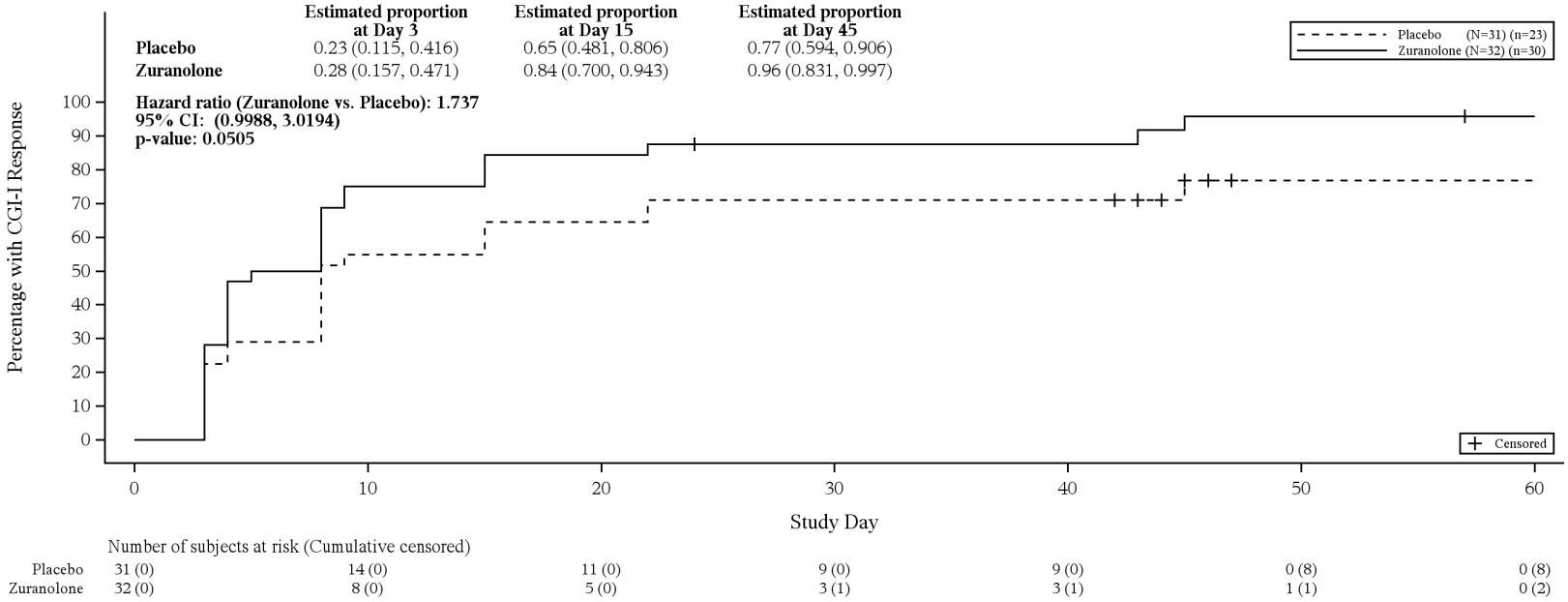
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = 3rd trimester

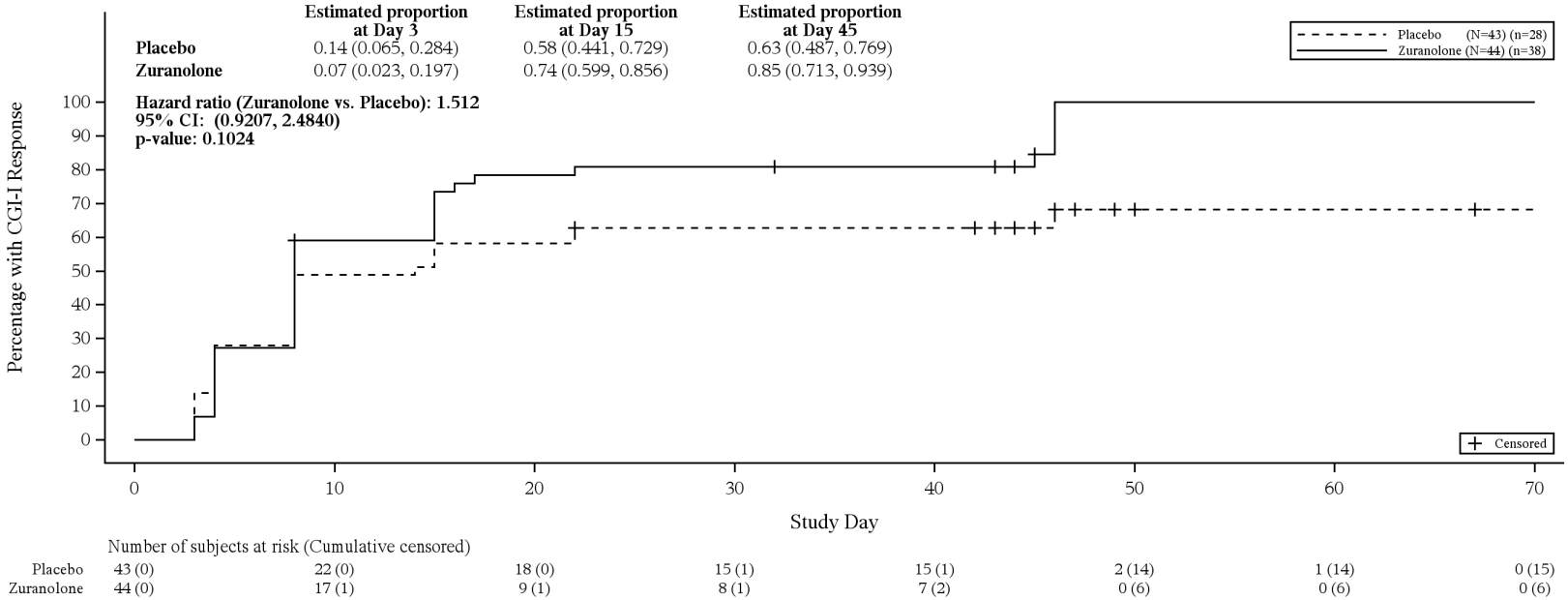


Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing CGI-I score at any visit.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.
Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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Onset of PPD = Postpartum



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

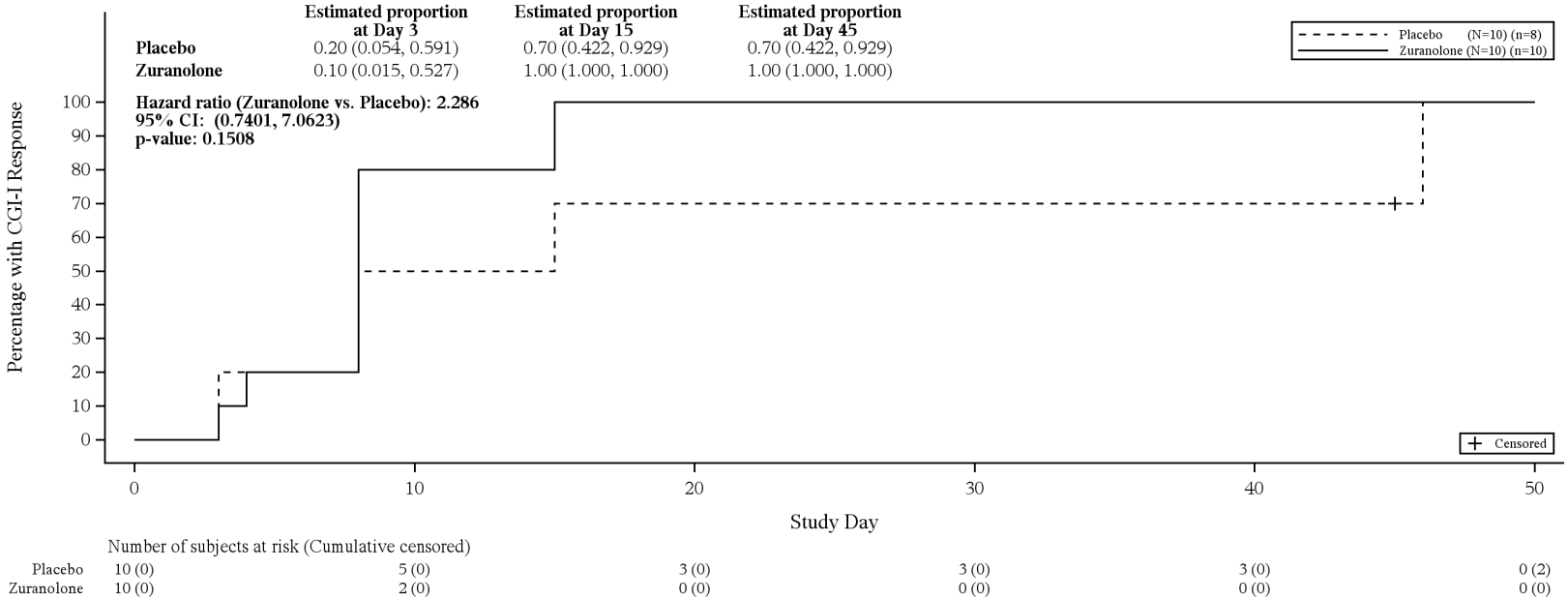
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = Yes



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

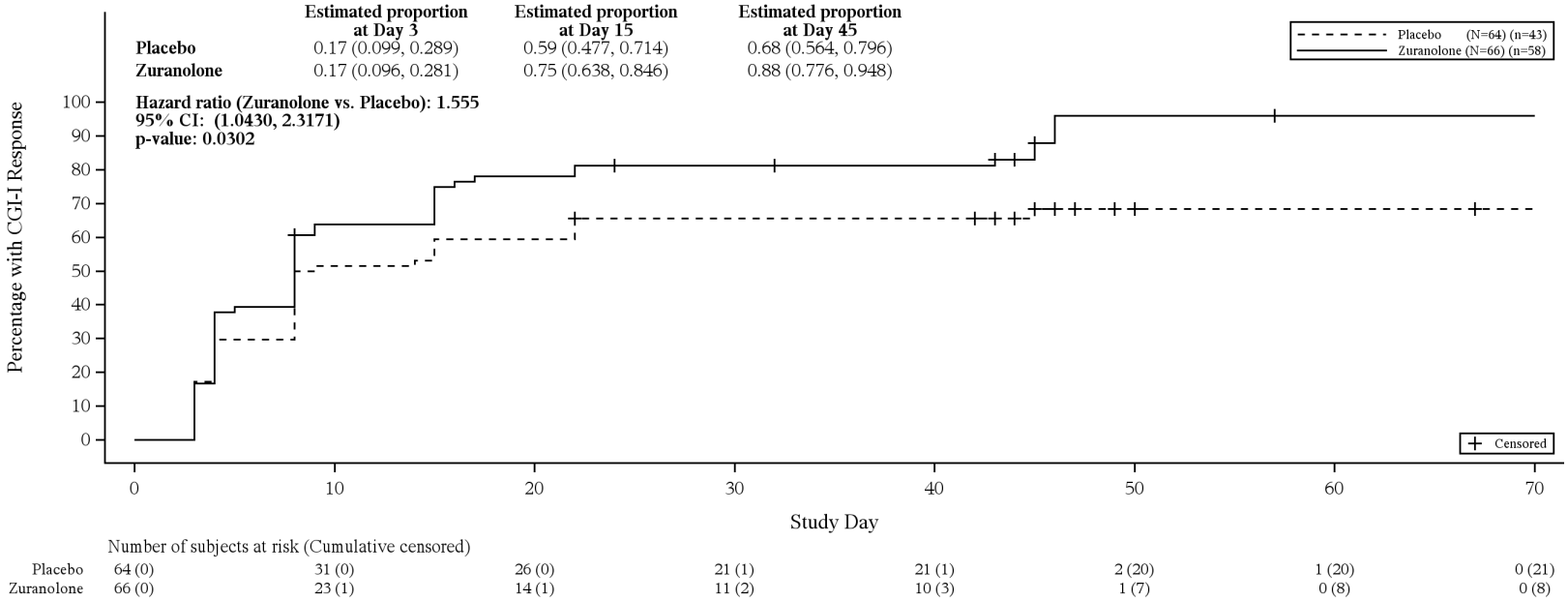
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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Family History of PPD = No/Unknown



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

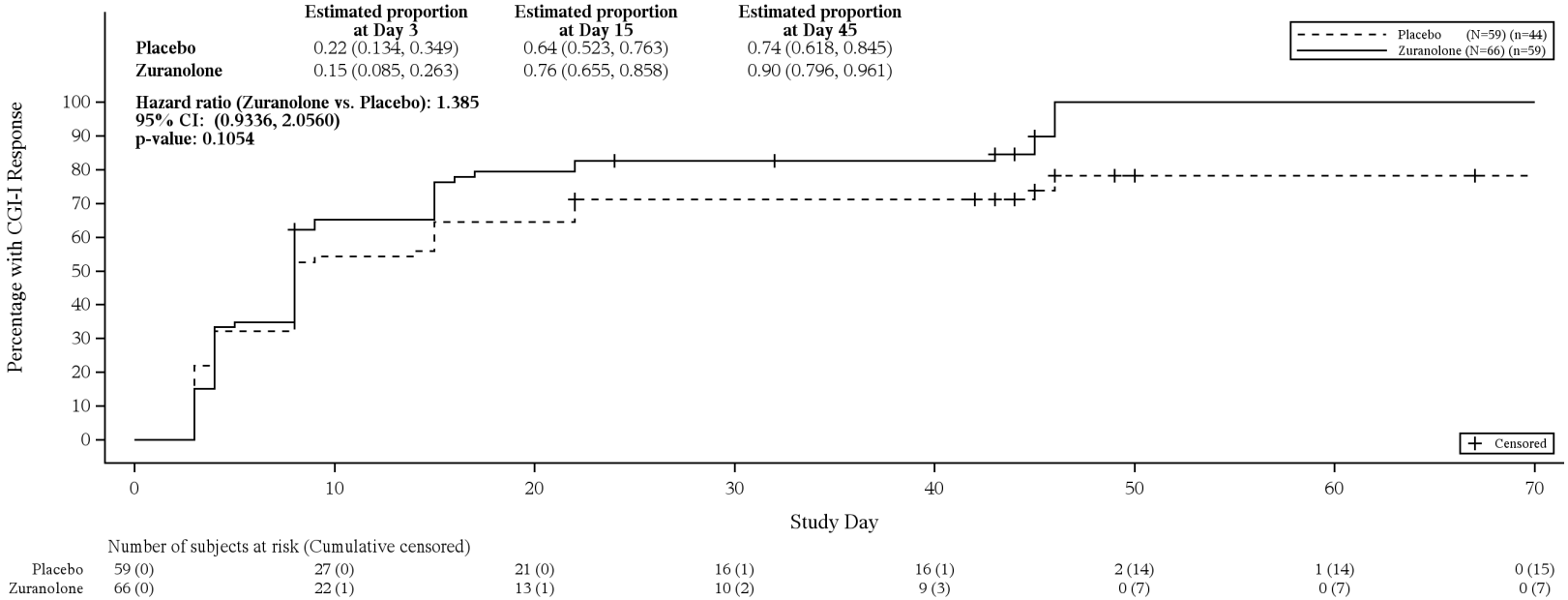
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Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = 1st Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

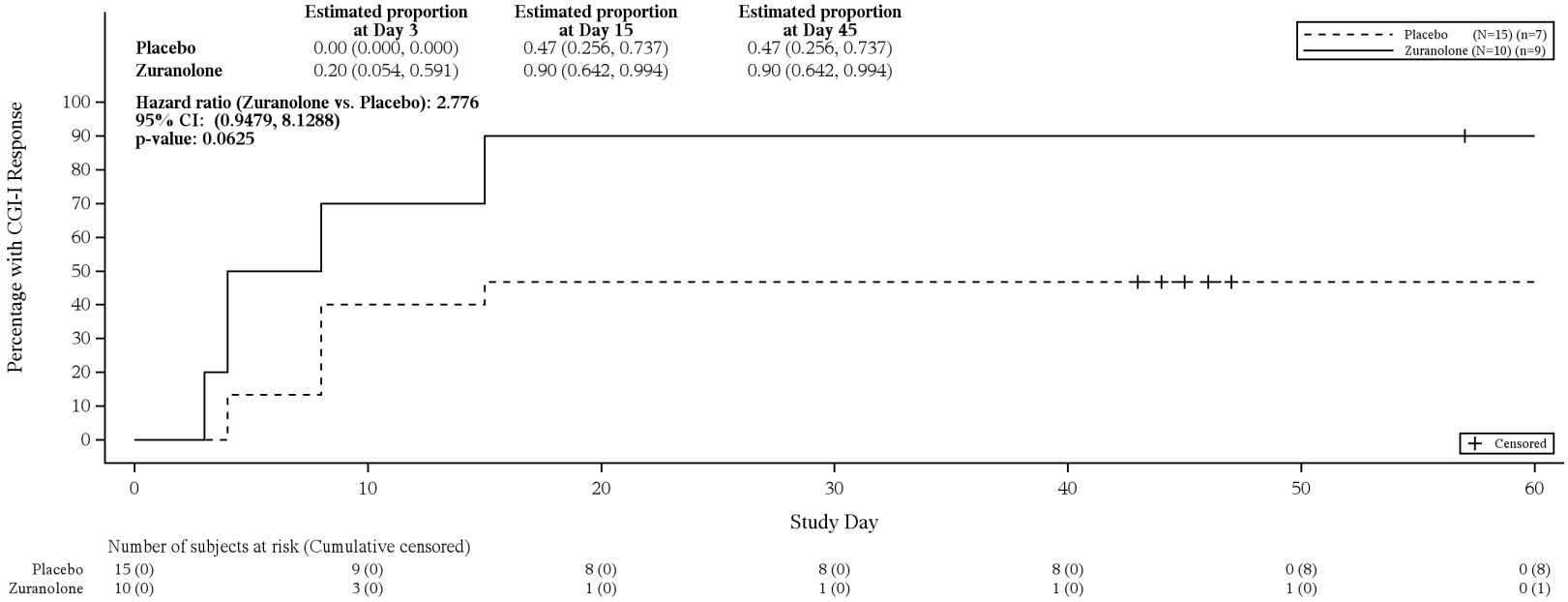
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-201B - ITT population

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History of PPD = Recurrent Episode



Abbreviations: N=number of evaluable subjects; n=number of subjects with response.

NOTE 1: Subjects with non-missing CGI-I score at any visit.

NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects are censored at the day of the last available evaluation if the event of interest is not observed.

NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-201-by.sas:f-cgii-resp12-tte-201-by-itta.rtf **Run Date:** 08JAN2026

5 Sicherheit

5.1 UE

5.1.1 Gesamtraten

5.1.1.1 ITT-Population

Number of Subjects with at Least One Treatment-Emergent Adverse Event: 217-PPD-201B - Safety population

Page: 1 of 1

	Placebo (N=73)	Zuranolone (N=78)
Number of subjects with >=1 TEAE, n (%)	38 (52.1)	47 (60.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.16
95% CI for the RR		(0.871, 1.539)
p-value for RR		0.3135
OR - Odds Ratio (Zuranolone vs. Placebo)		1.40
95% CI for the OR		(0.732, 2.663)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.076, 0.240)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-ovr.sas:t-ae-201-ovr-safc.rtf **Run Date:** 25JUL2025

5.1.1.2 Subgruppen

5.1.1.2 .1 Interaktionstest

Number of Subjects with at Least One Treatment-Emergent Adverse Event: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	38 (52.1)	47 (60.3)	
Age Group (years)			
18 - 24, n / N (%)	12/25 (48.0)	9/17 (52.9)	0.9820
25 - 45, n / N (%)	26/48 (54.2)	38/61 (62.3)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	8/21 (38.1)	20/31 (64.5)	0.1166
>=28, n / N (%)	30/52 (57.7)	27/47 (57.4)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	12/32 (37.5)	24/31 (77.4)	0.0018
White, n / N (%)	24/39 (61.5)	21/45 (46.7)	
Antidepressant Use at Baseline			
Yes, n / N (%)	8/13 (61.5)	11/16 (68.8)	0.9051
No, n / N (%)	30/60 (50.0)	36/62 (58.1)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-201-int.sas:t-ae-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

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Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	12/20 (60.0)	10/14 (71.4)	0.8574(a)
25-29.9, n / N (%)	7/19 (36.8)	11/22 (50.0)	0.6736(b)
>=30, n / N (%)	19/34 (55.9)	26/42 (61.9)	0.5996(c)
Onset of PPD			
3rd Trimester, n / N (%)	14/31 (45.2)	21/33 (63.6)	0.2414
Postpartum, n / N (%)	24/42 (57.1)	26/45 (57.8)	
Family History of PPD			
Yes, n / N (%)	5/10 (50.0)	5/10 (50.0)	0.6521
No/Unknown, n / N (%)	33/63 (52.4)	42/68 (61.8)	
History of PPD			
1st Episode, n / N (%)	30/57 (52.6)	41/68 (60.3)	0.9088
Recurrent Episode, n / N (%)	8/16 (50.0)	6/10 (60.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	4/8 (50.0)	5/10 (50.0)	NA
>=20, n / N (%)	34/65 (52.3)	42/68 (61.8)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-201-int.sas:t-ae-201-int-safc.rtf **Run Date:** 25JUL2025

5.1.1.2 .2 Subgruppenanalysen

5.1.1.2 .2 .1 Alter

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Age Group: 217-PPD-201B - Safety Population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=25)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	12 (48.0)	9 (52.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.10
95% CI for the RR		(0.602, 2.022)
p-value for RR		0.7514
OR - Odds Ratio (Zuranolone vs. Placebo)		1.22
95% CI for the OR		(0.355, 4.186)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.258, 0.357)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-age-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Age Group: 217-PPD-201B - Safety Population

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Age Group (years) = 25-45

	Placebo (N=48)	Zuranolone (N=61)
Number of subjects with >=1 TEAE, n (%)	26 (54.2)	38 (62.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.15
95% CI for the RR		(0.831, 1.592)
p-value for RR		0.3996
OR - Odds Ratio (Zuranolone vs. Placebo)		1.40
95% CI for the OR		(0.648, 3.015)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.105, 0.267)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-age-safc.rtf **Run Date:** 25JUL2025

5.1.1.2 .2 .2 Schwere der Erkrankung

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=21)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	8 (38.1)	20 (64.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.69
95% CI for the RR		(0.925, 3.100)
p-value for RR		0.0876
OR - Odds Ratio (Zuranolone vs. Placebo)		2.95
95% CI for the OR		(0.938, 9.309)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.26
95% CI for the ARR		(-0.003, 0.532)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=52)	Zuranolone (N=47)
Number of subjects with >=1 TEAE, n (%)	30 (57.7)	27 (57.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.710, 1.397)
p-value for RR		0.9803
OR - Odds Ratio (Zuranolone vs. Placebo)		0.99
95% CI for the OR		(0.446, 2.199)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.197, 0.193)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

5.1.1.2 .2 .3 Abstammung

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Race Group: 217-PPD-201B - Safety Population

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Race Group = Black or African American

	Placebo (N=32)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	12 (37.5)	24 (77.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.06
95% CI for the RR		(1.270, 3.357)
p-value for RR		0.0035
OR - Odds Ratio (Zuranolone vs. Placebo)		5.71
95% CI for the OR		(1.893, 17.253)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.40
95% CI for the ARR		(0.176, 0.622)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-race-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Race Group: 217-PPD-201B - Safety Population

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Race Group = White

	Placebo (N=39)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	24 (61.5)	21 (46.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.76
95% CI for the RR		(0.509, 1.130)
p-value for RR		0.1741
OR - Odds Ratio (Zuranolone vs. Placebo)		0.55
95% CI for the OR		(0.229, 1.307)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.15
95% CI for the ARR		(-0.360, 0.062)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-race-safc.rtf **Run Date:** 25JUL2025

5.1.1.2 .2 .4 Antidepressiva-Nutzung

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of subjects with >=1 TEAE, n (%)	8 (61.5)	11 (68.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.12
95% CI for the RR		(0.650, 1.921)
p-value for RR		0.6887
OR - Odds Ratio (Zuranolone vs. Placebo)		1.38
95% CI for the OR		(0.295, 6.402)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.276, 0.421)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-adt-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Antidepressant Use at Baseline = No

	Placebo (N=60)	Zuranolone (N=62)
Number of subjects with >=1 TEAE, n (%)	30 (50.0)	36 (58.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.16
95% CI for the RR		(0.835, 1.615)
p-value for RR		0.3742
OR - Odds Ratio (Zuranolone vs. Placebo)		1.38
95% CI for the OR		(0.678, 2.829)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.096, 0.257)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-adt-safc.rtf **Run Date:** 25JUL2025

5.1.1.2 .2 .5 BMI

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=20)	Zuranolone (N=14)
Number of subjects with >=1 TEAE, n (%)	12 (60.0)	10 (71.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.19
95% CI for the RR		(0.731, 1.939)
p-value for RR		0.4835
OR - Odds Ratio (Zuranolone vs. Placebo)		1.67
95% CI for the OR		(0.385, 7.209)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.11
95% CI for the ARR		(-0.205, 0.434)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=19)	Zuranolone (N=22)
Number of subjects with >=1 TEAE, n (%)	7 (36.8)	11 (50.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.36
95% CI for the RR		(0.659, 2.794)
p-value for RR		0.4071
OR - Odds Ratio (Zuranolone vs. Placebo)		1.71
95% CI for the OR		(0.490, 5.995)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.13
95% CI for the ARR		(-0.170, 0.433)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of subjects with >=1 TEAE, n (%)	19 (55.9)	26 (61.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.11
95% CI for the RR		(0.756, 1.622)
p-value for RR		0.5989
OR - Odds Ratio (Zuranolone vs. Placebo)		1.28
95% CI for the OR		(0.511, 3.219)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.06
95% CI for the ARR		(-0.162, 0.283)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

5.1.1.2 .2 .6 Beginn der PPD

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Onset of PPD: 217-PPD-201B - Safety Population

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Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	14 (45.2)	21 (63.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.41
95% CI for the RR		(0.884, 2.245)
p-value for RR		0.1490
OR - Odds Ratio (Zuranolone vs. Placebo)		2.13
95% CI for the OR		(0.780, 5.786)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.18
95% CI for the ARR		(-0.055, 0.425)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-onset-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Onset of PPD: 217-PPD-201B - Safety Population

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Onset of PPD = Postpartum

	Placebo (N=42)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	24 (57.1)	26 (57.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.01
95% CI for the RR		(0.704, 1.452)
p-value for RR		0.9523
OR - Odds Ratio (Zuranolone vs. Placebo)		1.03
95% CI for the OR		(0.438, 2.402)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.202, 0.214)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-onset-safc.rtf **Run Date:** 25JUL2025

5.1.1.2 .2 .7 PPD in der Familie

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Family History of PPD: 217-PPD-201B - Safety Population

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Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	5 (50.0)	5 (50.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.416, 2.403)
p-value for RR		1.0000
OR - Odds Ratio (Zuranolone vs. Placebo)		1.00
95% CI for the OR		(0.173, 5.772)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.438, 0.438)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Family History of PPD: 217-PPD-201B - Safety Population

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Family History of PPD = No/Unknown

	Placebo (N=63)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	33 (52.4)	42 (61.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.18
95% CI for the RR		(0.873, 1.593)
p-value for RR		0.2827
OR - Odds Ratio (Zuranolone vs. Placebo)		1.47
95% CI for the OR		(0.733, 2.944)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(-0.075, 0.263)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

5.1.1.2 .2 .8 PPD in der Anamnese

Number of Subjects with at Least One Treatment-Emergent Adverse Event by History of PPD: 217-PPD-201B - Safety Population

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History of PPD = 1st Episode

	Placebo (N=57)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	30 (52.6)	41 (60.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.15
95% CI for the RR		(0.838, 1.566)
p-value for RR		0.3944
OR - Odds Ratio (Zuranolone vs. Placebo)		1.37
95% CI for the OR		(0.671, 2.784)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.098, 0.251)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-hist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by History of PPD: 217-PPD-201B - Safety Population

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History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	8 (50.0)	6 (60.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.20
95% CI for the RR		(0.593, 2.427)
p-value for RR		0.6119
OR - Odds Ratio (Zuranolone vs. Placebo)		1.50
95% CI for the OR		(0.303, 7.432)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.10
95% CI for the ARR		(-0.290, 0.490)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-201-by.sas:t-ae-201-by-hist-safc.rtf **Run Date:** 25JUL2025

5.1.2 nach SOC

5.1.2.1 ITT-Population

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-201B - Safety population

Page: 1 of 4

Nervous system disorders

	Placebo (N=73)	Zuranolone (N=78)
Number of subjects with >=1 TEAE, n (%)	19 (26.0)	27 (34.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.33
95% CI for the RR		(0.813, 2.176)
p-value for RR		0.2565
OR - Odds Ratio (Zuranolone vs. Placebo)		1.50
95% CI for the OR		(0.747, 3.032)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(-0.060, 0.232)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: Includes system organ class >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm. SOC is presented in decreasing frequency of Zuranolone column.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-ovr.sas:t-ae-soc-201-ovr-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-201B - Safety population

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Gastrointestinal disorders

	Placebo (N=73)	Zuranolone (N=78)
Number of subjects with >=1 TEAE, n (%)	14 (19.2)	14 (17.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.94
95% CI for the RR		(0.480, 1.826)
p-value for RR		0.8460
OR - Odds Ratio (Zuranolone vs. Placebo)		0.92
95% CI for the OR		(0.406, 2.095)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.136, 0.112)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: Includes system organ class >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm. SOC is presented in decreasing frequency of Zuranolone column.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-ovr.sas:t-ae-soc-201-ovr-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-201B - Safety population

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Infections and infestations

	Placebo (N=73)	Zuranolone (N=78)
Number of subjects with >=1 TEAE, n (%)	6 (8.2)	12 (15.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.87
95% CI for the RR		(0.741, 4.728)
p-value for RR		0.1848
OR - Odds Ratio (Zuranolone vs. Placebo)		2.03
95% CI for the OR		(0.720, 5.728)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.030, 0.174)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: Includes system organ class >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm. SOC is presented in decreasing frequency of Zuranolone column.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-ovr.sas:t-ae-soc-201-ovr-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-201B - Safety population

Psychiatric disorders

	Placebo (N=73)	Zuranolone (N=78)
Number of subjects with >=1 TEAE, n (%)	10 (13.7)	2 (2.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.19
95% CI for the RR		(0.042, 0.826)
p-value for RR		0.0269
OR - Odds Ratio (Zuranolone vs. Placebo)		0.17
95% CI for the OR		(0.035, 0.785)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.11
95% CI for the ARR		(-0.198, -0.025)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: Includes system organ class >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm. SOC is presented in decreasing frequency of Zuranolone column.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-ovr.sas:t-ae-soc-201-ovr-safc.rtf **Run Date:** 25JUL2025

5.1.2.2 Subgruppen

5.1.2.2 .1 Interaktionstest

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

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Nervous system disorders

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	19 (26.0)	27 (34.6)	
Age Group (years)			
18 - 24, n / N (%)	4/25 (16.0)	4/17 (23.5)	0.7683
25 - 45, n / N (%)	15/48 (31.3)	23/61 (37.7)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	3/21 (14.3)	11/31 (35.5)	0.2463
>=28, n / N (%)	16/52 (30.8)	16/47 (34.0)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	5/32 (15.6)	14/31 (45.2)	0.0463
White, n / N (%)	13/39 (33.3)	12/45 (26.7)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function and "Poisson" distribution. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes SOC >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-int.sas:t-ae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

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Nervous system disorders

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	5/13 (38.5)	7/16 (43.8)	0.7753
No, n / N (%)	14/60 (23.3)	20/62 (32.3)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	7/20 (35.0)	6/14 (42.9)	0.8695(a)
25-29.9, n / N (%)	3/19 (15.8)	5/22 (22.7)	0.8399(b)
>=30, n / N (%)	9/34 (26.5)	16/42 (38.1)	0.9903(c)
Onset of PPD			
3rd Trimester, n / N (%)	7/31 (22.6)	13/33 (39.4)	0.3882
Postpartum, n / N (%)	12/42 (28.6)	14/45 (31.1)	
Family History of PPD			
Yes, n / N (%)	2/10 (20.0)	4/10 (40.0)	0.7100
No/Unknown, n / N (%)	17/63 (27.0)	23/68 (33.8)	

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function and "Poisson" distribution. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).

NOTE 4: Includes SOC >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-int.sas:t-ae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

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Nervous system disorders

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	15/57 (26.3)	23/68 (33.8)	0.8992
Recurrent Episode, n / N (%)	4/16 (25.0)	4/10 (40.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
>=20, n / N (%)	15/65 (23.1)	26/68 (38.2)	NA
<20, n / N (%)	4/8 (50.0)	1/10 (10.0)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function and "Poisson" distribution. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes SOC >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-int.sas:t-ae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	14 (19.2)	14 (17.9)	
Age Group (years)			
18 - 24, n / N (%)	7/25 (28.0)	5/17 (29.4)	NA
25 - 45, n / N (%)	7/48 (14.6)	9/61 (14.8)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	5/21 (23.8)	8/31 (25.8)	NA
>=28, n / N (%)	9/52 (17.3)	6/47 (12.8)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	4/32 (12.5)	9/31 (29.0)	0.0352
White, n / N (%)	10/39 (25.6)	5/45 (11.1)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function and "Poisson" distribution. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes SOC >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-int.sas:t-ae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	6/13 (46.2)	3/16 (18.8)	0.1506
No, n / N (%)	8/60 (13.3)	11/62 (17.7)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	5/20 (25.0)	5/14 (35.7)	NA(a)
25-29.9, n / N (%)	3/19 (15.8)	2/22 (9.1)	NA(b)
>=30, n / N (%)	6/34 (17.6)	7/42 (16.7)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	3/31 (9.7)	6/33 (18.2)	0.1787
Postpartum, n / N (%)	11/42 (26.2)	8/45 (17.8)	
Family History of PPD			
Yes, n / N (%)	1/10 (10.0)	1/10 (10.0)	0.8983
No/Unknown, n / N (%)	13/63 (20.6)	13/68 (19.1)	

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function and "Poisson" distribution. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).

NOTE 4: Includes SOC >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-int.sas:t-ae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	11/57 (19.3)	12/68 (17.6)	0.9366
Recurrent Episode, n / N (%)	3/16 (18.8)	2/10 (20.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
>=20, n / N (%)	12/65 (18.5)	12/68 (17.6)	NA
<20, n / N (%)	2/8 (25.0)	2/10 (20.0)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function and "Poisson" distribution. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes SOC >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-int.sas:t-ae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

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Infections and infestations

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	6 (8.2)	12 (15.4)	
Age Group (years)			
18 - 24, n / N (%)	2/25 (8.0)	1/17 (5.9)	0.3796
25 - 45, n / N (%)	4/48 (8.3)	11/61 (18.0)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	1/21 (4.8)	4/31 (12.9)	NA
>=28, n / N (%)	5/52 (9.6)	8/47 (17.0)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	1/32 (3.1)	7/31 (22.6)	NA
White, n / N (%)	5/39 (12.8)	5/45 (11.1)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function and "Poisson" distribution. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes SOC >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-int.sas:t-ae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

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Infections and infestations

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	0/13	1/16 (6.3)	0.8421
No, n / N (%)	6/60 (10.0)	11/62 (17.7)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	3/20 (15.0)	0/14	NA(a)
25-29.9, n / N (%)	0/19	4/22 (18.2)	NA(b)
>=30, n / N (%)	3/34 (8.8)	8/42 (19.0)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	2/31 (6.5)	8/33 (24.2)	NA
Postpartum, n / N (%)	4/42 (9.5)	4/45 (8.9)	
Family History of PPD			
Yes, n / N (%)	1/10 (10.0)	0/10	0.2514
No/Unknown, n / N (%)	5/63 (7.9)	12/68 (17.6)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function and "Poisson" distribution. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes SOC >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-int.sas:t-ae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

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Infections and infestations

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	4/57 (7.0)	12/68 (17.6)	0.1894
Recurrent Episode, n / N (%)	2/16 (12.5)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
>=20, n / N (%)	6/65 (9.2)	11/68 (16.2)	NA
<20, n / N (%)	0/8	1/10 (10.0)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function and "Poisson" distribution. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes SOC >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-int.sas:t-ae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

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Psychiatric disorders

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	10 (13.7)	2 (2.6)	
Age Group (years)			
18 - 24, n / N (%)	5/25 (20.0)	1/17 (5.9)	NA
25 - 45, n / N (%)	5/48 (10.4)	1/61 (1.6)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	2/21 (9.5)	1/31 (3.2)	NA
>=28, n / N (%)	8/52 (15.4)	1/47 (2.1)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	2/32 (6.3)	1/31 (3.2)	NA
White, n / N (%)	8/39 (20.5)	1/45 (2.2)	

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function and "Poisson" distribution. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).

NOTE 4: Includes SOC >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-int.sas:t-ae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

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Psychiatric disorders

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	2/13 (15.4)	0/16	NA
No, n / N (%)	8/60 (13.3)	2/62 (3.2)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	3/20 (15.0)	1/14 (7.1)	NA(a)
25-29.9, n / N (%)	3/19 (15.8)	0/22	NA(b)
>=30, n / N (%)	4/34 (11.8)	1/42 (2.4)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	5/31 (16.1)	0/33	NA
Postpartum, n / N (%)	5/42 (11.9)	2/45 (4.4)	
Family History of PPD			
Yes, n / N (%)	1/10 (10.0)	0/10	NA
No/Unknown, n / N (%)	9/63 (14.3)	2/68 (2.9)	

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function and "Poisson" distribution. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).

NOTE 4: Includes SOC >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-int.sas:t-ae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

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Psychiatric disorders

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	8/57 (14.0)	2/68 (2.9)	NA
Recurrent Episode, n / N (%)	2/16 (12.5)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
>=20, n / N (%)	9/65 (13.8)	2/68 (2.9)	NA
<20, n / N (%)	1/8 (12.5)	0/10	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function and "Poisson" distribution. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes SOC >=10% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-int.sas:t-ae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

5.1.2.2 .2 Subgruppenanalysen

5.1.2.2 .2 .1 Alter

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-201B - Safety Population

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Nervous system disorders

Age Group (years) = 18-24

	Placebo (N=25)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	4 (16.0)	4 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.47
95% CI for the RR		(0.425, 5.089)
p-value for RR		0.5426
OR - Odds Ratio (Zuranolone vs. Placebo)		1.62
95% CI for the OR		(0.343, 7.603)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.172, 0.323)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-age-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-201B - Safety Population

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Nervous system disorders

Age Group (years) = 25-45

	Placebo (N=48)	Zuranolone (N=61)
Number of subjects with >=1 TEAE, n (%)	15 (31.3)	23 (37.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.21
95% CI for the RR		(0.711, 2.048)
p-value for RR		0.4868
OR - Odds Ratio (Zuranolone vs. Placebo)		1.33
95% CI for the OR		(0.598, 2.965)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.06
95% CI for the ARR		(-0.114, 0.243)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-age-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Age Group (years) = 18-24

	Placebo (N=25)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	7 (28.0)	5 (29.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.05
95% CI for the RR		(0.399, 2.766)
p-value for RR		0.9207
OR - Odds Ratio (Zuranolone vs. Placebo)		1.07
95% CI for the OR		(0.275, 4.176)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.265, 0.293)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-age-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Age Group (years) = 25-45

	Placebo (N=48)	Zuranolone (N=61)
Number of subjects with >=1 TEAE, n (%)	7 (14.6)	9 (14.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.01
95% CI for the RR		(0.406, 2.520)
p-value for RR		0.9801
OR - Odds Ratio (Zuranolone vs. Placebo)		1.01
95% CI for the OR		(0.348, 2.953)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.132, 0.135)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-age-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-201B - Safety Population

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Infections and infestations

Age Group (years) = 18-24

	Placebo (N=25)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	2 (8.0)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.74
95% CI for the RR		(0.072, 7.482)
p-value for RR		0.7950
OR - Odds Ratio (Zuranolone vs. Placebo)		0.72
95% CI for the OR		(0.060, 8.616)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.02
95% CI for the ARR		(-0.176, 0.133)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-age-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-201B - Safety Population

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Infections and infestations

Age Group (years) = 25-45

	Placebo (N=48)	Zuranolone (N=61)
Number of subjects with >=1 TEAE, n (%)	4 (8.3)	11 (18.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.16
95% CI for the RR		(0.735, 6.373)
p-value for RR		0.1613
OR - Odds Ratio (Zuranolone vs. Placebo)		2.42
95% CI for the OR		(0.719, 8.148)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.10
95% CI for the ARR		(-0.027, 0.221)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-age-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-201B - Safety Population

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Psychiatric disorders

Age Group (years) = 18-24

	Placebo (N=25)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	5 (20.0)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.29
95% CI for the RR		(0.038, 2.300)
p-value for RR		0.2435
OR - Odds Ratio (Zuranolone vs. Placebo)		0.25
95% CI for the OR		(0.026, 2.361)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.14
95% CI for the ARR		(-0.334, 0.051)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-age-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-201B - Safety Population

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Psychiatric disorders

Age Group (years) = 25-45

	Placebo (N=48)	Zuranolone (N=61)
Number of subjects with >=1 TEAE, n (%)	5 (10.4)	1 (1.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.16
95% CI for the RR		(0.019, 1.303)
p-value for RR		0.0864
OR - Odds Ratio (Zuranolone vs. Placebo)		0.14
95% CI for the OR		(0.016, 1.271)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.180, 0.004)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-age-safc.rtf **Run Date:** 25JUL2025

5.1.2.2 .2 .2 Schwere der Erkrankung

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Nervous system disorders

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=21)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	3 (14.3)	11 (35.5)
RR - Relative Risk (Zuranolone vs. Placebo)		2.48
95% CI for the RR		(0.786, 7.846)
p-value for RR		0.1210
OR - Odds Ratio (Zuranolone vs. Placebo)		3.30
95% CI for the OR		(0.792, 13.743)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.21
95% CI for the ARR		(-0.013, 0.437)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Nervous system disorders

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=52)	Zuranolone (N=47)
Number of subjects with >=1 TEAE, n (%)	16 (30.8)	16 (34.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.11
95% CI for the RR		(0.626, 1.956)
p-value for RR		0.7280
OR - Odds Ratio (Zuranolone vs. Placebo)		1.16
95% CI for the OR		(0.500, 2.698)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.152, 0.217)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=21)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	5 (23.8)	8 (25.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.08
95% CI for the RR		(0.411, 2.860)
p-value for RR		0.8708
OR - Odds Ratio (Zuranolone vs. Placebo)		1.11
95% CI for the OR		(0.307, 4.030)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.219, 0.259)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=52)	Zuranolone (N=47)
Number of subjects with >=1 TEAE, n (%)	9 (17.3)	6 (12.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.74
95% CI for the RR		(0.284, 1.916)
p-value for RR		0.5321
OR - Odds Ratio (Zuranolone vs. Placebo)		0.70
95% CI for the OR		(0.229, 2.139)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.05
95% CI for the ARR		(-0.186, 0.095)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Infections and infestations

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=21)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	1 (4.8)	4 (12.9)
RR - Relative Risk (Zuranolone vs. Placebo)		2.71
95% CI for the RR		(0.325, 22.578)
p-value for RR		0.3568
OR - Odds Ratio (Zuranolone vs. Placebo)		2.96
95% CI for the OR		(0.307, 28.574)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.068, 0.230)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Infections and infestations

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=52)	Zuranolone (N=47)
Number of subjects with >=1 TEAE, n (%)	5 (9.6)	8 (17.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.77
95% CI for the RR		(0.622, 5.035)
p-value for RR		0.2843
OR - Odds Ratio (Zuranolone vs. Placebo)		1.93
95% CI for the OR		(0.584, 6.372)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.060, 0.208)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Psychiatric disorders

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=21)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	2 (9.5)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.34
95% CI for the RR		(0.033, 3.501)
p-value for RR		0.3636
OR - Odds Ratio (Zuranolone vs. Placebo)		0.32
95% CI for the OR		(0.027, 3.737)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.06
95% CI for the ARR		(-0.203, 0.077)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Psychiatric disorders

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=52)	Zuranolone (N=47)
Number of subjects with >=1 TEAE, n (%)	8 (15.4)	1 (2.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.14
95% CI for the RR		(0.018, 1.065)
p-value for RR		0.0575
OR - Odds Ratio (Zuranolone vs. Placebo)		0.12
95% CI for the OR		(0.014, 0.996)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.13
95% CI for the ARR		(-0.239, -0.026)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

5.1.2.2 .2 .3 Abstammung

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-201B - Safety Population

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Nervous system disorders

Race Group = Black or African American

	Placebo (N=32)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	5 (15.6)	14 (45.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.89
95% CI for the RR		(1.183, 7.064)
p-value for RR		0.0199
OR - Odds Ratio (Zuranolone vs. Placebo)		4.45
95% CI for the OR		(1.356, 14.586)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.30
95% CI for the ARR		(0.080, 0.511)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-race-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-201B - Safety Population

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Nervous system disorders

Race Group = White

	Placebo (N=39)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	13 (33.3)	12 (26.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.80
95% CI for the RR		(0.415, 1.543)
p-value for RR		0.5057
OR - Odds Ratio (Zuranolone vs. Placebo)		0.73
95% CI for the OR		(0.285, 1.858)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.07
95% CI for the ARR		(-0.263, 0.130)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-race-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-201B - Safety Population

Page: 3 of 8

Gastrointestinal disorders

Race Group = Black or African American

	Placebo (N=32)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	4 (12.5)	9 (29.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.32
95% CI for the RR		(0.797, 6.766)
p-value for RR		0.1224
OR - Odds Ratio (Zuranolone vs. Placebo)		2.86
95% CI for the OR		(0.778, 10.544)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.17
95% CI for the ARR		(-0.031, 0.362)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-race-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Race Group = White

	Placebo (N=39)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	10 (25.6)	5 (11.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.43
95% CI for the RR		(0.162, 1.159)
p-value for RR		0.0958
OR - Odds Ratio (Zuranolone vs. Placebo)		0.36
95% CI for the OR		(0.112, 1.174)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.15
95% CI for the ARR		(-0.310, 0.020)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-race-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-201B - Safety Population

Page: 5 of 8

Infections and infestations

Race Group = Black or African American

	Placebo (N=32)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	1 (3.1)	7 (22.6)
RR - Relative Risk (Zuranolone vs. Placebo)		7.23
95% CI for the RR		(0.943, 55.362)
p-value for RR		0.0570
OR - Odds Ratio (Zuranolone vs. Placebo)		9.04
95% CI for the OR		(1.041, 78.558)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.19
95% CI for the ARR		(0.036, 0.354)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-race-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-201B - Safety Population

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Infections and infestations

Race Group = White

	Placebo (N=39)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	5 (12.8)	5 (11.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.87
95% CI for the RR		(0.271, 2.773)
p-value for RR		0.8094
OR - Odds Ratio (Zuranolone vs. Placebo)		0.85
95% CI for the OR		(0.227, 3.186)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.02
95% CI for the ARR		(-0.157, 0.122)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-race-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-201B - Safety Population

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Psychiatric disorders

Race Group = Black or African American

	Placebo (N=32)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	2 (6.3)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.52
95% CI for the RR		(0.049, 5.407)
p-value for RR		0.5811
OR - Odds Ratio (Zuranolone vs. Placebo)		0.50
95% CI for the OR		(0.043, 5.813)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.135, 0.074)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-race-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-201B - Safety Population

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Psychiatric disorders

Race Group = White

	Placebo (N=39)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	8 (20.5)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.11
95% CI for the RR		(0.014, 0.828)
p-value for RR		0.0322
OR - Odds Ratio (Zuranolone vs. Placebo)		0.09
95% CI for the OR		(0.010, 0.740)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.18
95% CI for the ARR		(-0.317, -0.049)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-race-safc.rtf **Run Date:** 25JUL2025

5.1.2.2 .2 .4 Antidepressiva-Nutzung

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Nervous system disorders

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of subjects with >=1 TEAE, n (%)	5 (38.5)	7 (43.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.14
95% CI for the RR		(0.470, 2.753)
p-value for RR		0.7752
OR - Odds Ratio (Zuranolone vs. Placebo)		1.24
95% CI for the OR		(0.280, 5.529)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.306, 0.412)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-adt-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Nervous system disorders

Antidepressant Use at Baseline = No

	Placebo (N=60)	Zuranolone (N=62)
Number of subjects with >=1 TEAE, n (%)	14 (23.3)	20 (32.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.38
95% CI for the RR		(0.771, 2.478)
p-value for RR		0.2766
OR - Odds Ratio (Zuranolone vs. Placebo)		1.56
95% CI for the OR		(0.702, 3.485)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(-0.069, 0.247)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-adt-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of subjects with >=1 TEAE, n (%)	6 (46.2)	3 (18.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.41
95% CI for the RR		(0.125, 1.318)
p-value for RR		0.1336
OR - Odds Ratio (Zuranolone vs. Placebo)		0.27
95% CI for the OR		(0.051, 1.420)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.27
95% CI for the ARR		(-0.606, 0.058)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-adt-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Antidepressant Use at Baseline = No

	Placebo (N=60)	Zuranolone (N=62)
Number of subjects with >=1 TEAE, n (%)	8 (13.3)	11 (17.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.33
95% CI for the RR		(0.575, 3.078)
p-value for RR		0.5044
OR - Odds Ratio (Zuranolone vs. Placebo)		1.40
95% CI for the OR		(0.521, 3.770)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.084, 0.172)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-adt-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Infections and infestations

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of subjects with >=1 TEAE, n (%)	0	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.47
95% CI for the RR		(0.109, 56.032)
p-value for RR		0.5701
OR - Odds Ratio (Zuranolone vs. Placebo)		2.61
95% CI for the OR		(0.098, 69.629)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.114, 0.219)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-adt-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Infections and infestations

Antidepressant Use at Baseline = No

	Placebo (N=60)	Zuranolone (N=62)
Number of subjects with >=1 TEAE, n (%)	6 (10.0)	11 (17.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.77
95% CI for the RR		(0.701, 4.493)
p-value for RR		0.2265
OR - Odds Ratio (Zuranolone vs. Placebo)		1.94
95% CI for the OR		(0.669, 5.636)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.044, 0.199)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-adt-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Psychiatric disorders

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of subjects with >=1 TEAE, n (%)	2 (15.4)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.16
95% CI for the RR		(0.009, 3.156)
p-value for RR		0.2312
OR - Odds Ratio (Zuranolone vs. Placebo)		0.14
95% CI for the OR		(0.006, 3.183)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.15
95% CI for the ARR		(-0.365, 0.067)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-adt-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Psychiatric disorders

Antidepressant Use at Baseline = No

	Placebo (N=60)	Zuranolone (N=62)
Number of subjects with >=1 TEAE, n (%)	8 (13.3)	2 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.24
95% CI for the RR		(0.054, 1.093)
p-value for RR		0.0652
OR - Odds Ratio (Zuranolone vs. Placebo)		0.22
95% CI for the OR		(0.044, 1.066)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.10
95% CI for the ARR		(-0.198, -0.004)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-adt-safc.rtf **Run Date:** 25JUL2025

5.1.2.2 .2 .5 BMI

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Nervous system disorders

BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=20)	Zuranolone (N=14)
Number of subjects with >=1 TEAE, n (%)	7 (35.0)	6 (42.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.22
95% CI for the RR		(0.523, 2.865)
p-value for RR		0.6405
OR - Odds Ratio (Zuranolone vs. Placebo)		1.39
95% CI for the OR		(0.343, 5.658)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.254, 0.412)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Nervous system disorders

BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=19)	Zuranolone (N=22)
Number of subjects with >=1 TEAE, n (%)	3 (15.8)	5 (22.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.44
95% CI for the RR		(0.395, 5.245)
p-value for RR		0.5809
OR - Odds Ratio (Zuranolone vs. Placebo)		1.57
95% CI for the OR		(0.321, 7.660)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.171, 0.309)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Nervous system disorders

BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of subjects with >=1 TEAE, n (%)	9 (26.5)	16 (38.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.44
95% CI for the RR		(0.729, 2.841)
p-value for RR		0.2941
OR - Odds Ratio (Zuranolone vs. Placebo)		1.71
95% CI for the OR		(0.639, 4.573)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.12
95% CI for the ARR		(-0.092, 0.325)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=20)	Zuranolone (N=14)
Number of subjects with >=1 TEAE, n (%)	5 (25.0)	5 (35.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.43
95% CI for the RR		(0.508, 4.019)
p-value for RR		0.4992
OR - Odds Ratio (Zuranolone vs. Placebo)		1.67
95% CI for the OR		(0.376, 7.394)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.11
95% CI for the ARR		(-0.208, 0.422)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

Page: 5 of 12

Gastrointestinal disorders

BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=19)	Zuranolone (N=22)
Number of subjects with >=1 TEAE, n (%)	3 (15.8)	2 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.58
95% CI for the RR		(0.107, 3.091)
p-value for RR		0.5197
OR - Odds Ratio (Zuranolone vs. Placebo)		0.53
95% CI for the OR		(0.079, 3.588)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.07
95% CI for the ARR		(-0.270, 0.136)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of subjects with >=1 TEAE, n (%)	6 (17.6)	7 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.94
95% CI for the RR		(0.350, 2.547)
p-value for RR		0.9101
OR - Odds Ratio (Zuranolone vs. Placebo)		0.93
95% CI for the OR		(0.282, 3.094)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.180, 0.161)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Infections and infestations

BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=20)	Zuranolone (N=14)
Number of subjects with >=1 TEAE, n (%)	3 (15.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.20
95% CI for the RR		(0.011, 3.592)
p-value for RR		0.2747
OR - Odds Ratio (Zuranolone vs. Placebo)		0.17
95% CI for the OR		(0.008, 3.618)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.13
95% CI for the ARR		(-0.317, 0.050)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Infections and infestations

BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=19)	Zuranolone (N=22)
Number of subjects with >=1 TEAE, n (%)	0	4 (18.2)
RR - Relative Risk (Zuranolone vs. Placebo)		7.83
95% CI for the RR		(0.448, 136.605)
p-value for RR		0.1585
OR - Odds Ratio (Zuranolone vs. Placebo)		9.49
95% CI for the OR		(0.477, 188.681)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.17
95% CI for the ARR		(-0.005, 0.347)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Infections and infestations

BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of subjects with >=1 TEAE, n (%)	3 (8.8)	8 (19.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.16
95% CI for the RR		(0.620, 7.516)
p-value for RR		0.2267
OR - Odds Ratio (Zuranolone vs. Placebo)		2.43
95% CI for the OR		(0.592, 9.992)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.10
95% CI for the ARR		(-0.050, 0.255)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Psychiatric disorders

BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=20)	Zuranolone (N=14)
Number of subjects with >=1 TEAE, n (%)	3 (15.0)	1 (7.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.48
95% CI for the RR		(0.055, 4.119)
p-value for RR		0.5003
OR - Odds Ratio (Zuranolone vs. Placebo)		0.44
95% CI for the OR		(0.041, 4.689)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.08
95% CI for the ARR		(-0.285, 0.128)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Psychiatric disorders

BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=19)	Zuranolone (N=22)
Number of subjects with >=1 TEAE, n (%)	3 (15.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.12
95% CI for the RR		(0.007, 2.262)
p-value for RR		0.1589
OR - Odds Ratio (Zuranolone vs. Placebo)		0.10
95% CI for the OR		(0.005, 2.169)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.15
95% CI for the ARR		(-0.330, 0.024)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Psychiatric disorders

BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of subjects with >=1 TEAE, n (%)	4 (11.8)	1 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.20
95% CI for the RR		(0.024, 1.727)
p-value for RR		0.1442
OR - Odds Ratio (Zuranolone vs. Placebo)		0.18
95% CI for the OR		(0.019, 1.721)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.212, 0.024)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

5.1.2.2 .2 .6 Beginn der PPD

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	7 (22.6)	13 (39.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.74
95% CI for the RR		(0.802, 3.795)
p-value for RR		0.1605
OR - Odds Ratio (Zuranolone vs. Placebo)		2.23
95% CI for the OR		(0.746, 6.654)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.17
95% CI for the ARR		(-0.054, 0.391)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-onset-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders

Onset of PPD = Postpartum

	Placebo (N=42)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	12 (28.6)	14 (31.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.09
95% CI for the RR		(0.571, 2.078)
p-value for RR		0.7962
OR - Odds Ratio (Zuranolone vs. Placebo)		1.13
95% CI for the OR		(0.450, 2.833)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.167, 0.218)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-onset-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	3 (9.7)	6 (18.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.88
95% CI for the RR		(0.514, 6.868)
p-value for RR		0.3403
OR - Odds Ratio (Zuranolone vs. Placebo)		2.07
95% CI for the OR		(0.471, 9.141)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(-0.083, 0.253)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-onset-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Onset of PPD = Postpartum

	Placebo (N=42)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	11 (26.2)	8 (17.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.68
95% CI for the RR		(0.303, 1.523)
p-value for RR		0.3472
OR - Odds Ratio (Zuranolone vs. Placebo)		0.61
95% CI for the OR		(0.218, 1.704)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.08
95% CI for the ARR		(-0.258, 0.090)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-onset-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-201B - Safety Population

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Infections and infestations

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	2 (6.5)	8 (24.2)
RR - Relative Risk (Zuranolone vs. Placebo)		3.76
95% CI for the RR		(0.864, 16.341)
p-value for RR		0.0775
OR - Odds Ratio (Zuranolone vs. Placebo)		4.64
95% CI for the OR		(0.901, 23.901)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.18
95% CI for the ARR		(0.008, 0.348)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-onset-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-201B - Safety Population

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Infections and infestations

Onset of PPD = Postpartum

	Placebo (N=42)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	4 (9.5)	4 (8.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.93
95% CI for the RR		(0.249, 3.496)
p-value for RR		0.9184
OR - Odds Ratio (Zuranolone vs. Placebo)		0.93
95% CI for the OR		(0.216, 3.969)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.128, 0.115)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-onset-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-201B - Safety Population

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Psychiatric disorders

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	5 (16.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.09
95% CI for the RR		(0.005, 1.486)
p-value for RR		0.0914
OR - Odds Ratio (Zuranolone vs. Placebo)		0.07
95% CI for the OR		(0.004, 1.360)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.16
95% CI for the ARR		(-0.294, -0.020)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-onset-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-201B - Safety Population

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Psychiatric disorders

Onset of PPD = Postpartum

	Placebo (N=42)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	5 (11.9)	2 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.37
95% CI for the RR		(0.077, 1.822)
p-value for RR		0.2231
OR - Odds Ratio (Zuranolone vs. Placebo)		0.34
95% CI for the OR		(0.063, 1.880)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.07
95% CI for the ARR		(-0.190, 0.040)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-onset-safc.rtf **Run Date:** 25JUL2025

5.1.2.2 .2 .7 PPD in der Familie

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	2 (20.0)	4 (40.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.00
95% CI for the RR		(0.467, 8.557)
p-value for RR		0.3500
OR - Odds Ratio (Zuranolone vs. Placebo)		2.67
95% CI for the OR		(0.361, 19.712)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.20
95% CI for the ARR		(-0.192, 0.592)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders

Family History of PPD = No/Unknown

	Placebo (N=63)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	17 (27.0)	23 (33.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.25
95% CI for the RR		(0.742, 2.119)
p-value for RR		0.3989
OR - Odds Ratio (Zuranolone vs. Placebo)		1.38
95% CI for the OR		(0.654, 2.927)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.089, 0.225)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	1 (10.0)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.072, 13.868)
p-value for RR		1.0000
OR - Odds Ratio (Zuranolone vs. Placebo)		1.00
95% CI for the OR		(0.054, 18.574)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.263, 0.263)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

Family History of PPD = No/Unknown

	Placebo (N=63)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	13 (20.6)	13 (19.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.93
95% CI for the RR		(0.466, 1.844)
p-value for RR		0.8278
OR - Odds Ratio (Zuranolone vs. Placebo)		0.91
95% CI for the OR		(0.385, 2.146)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.02
95% CI for the ARR		(-0.152, 0.122)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-201B - Safety Population

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Infections and infestations

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.015, 7.323)
p-value for RR		0.4858
OR - Odds Ratio (Zuranolone vs. Placebo)		0.30
95% CI for the OR		(0.011, 8.332)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.328, 0.146)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-201B - Safety Population

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Infections and infestations

Family History of PPD = No/Unknown

	Placebo (N=63)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	5 (7.9)	12 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		2.22
95% CI for the RR		(0.830, 5.956)
p-value for RR		0.1120
OR - Odds Ratio (Zuranolone vs. Placebo)		2.49
95% CI for the OR		(0.822, 7.512)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.10
95% CI for the ARR		(-0.015, 0.210)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-201B - Safety Population

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Psychiatric disorders

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.015, 7.323)
p-value for RR		0.4858
OR - Odds Ratio (Zuranolone vs. Placebo)		0.30
95% CI for the OR		(0.011, 8.332)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.328, 0.146)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-201B - Safety Population

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Psychiatric disorders

Family History of PPD = No/Unknown

	Placebo (N=63)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	9 (14.3)	2 (2.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.21
95% CI for the RR		(0.046, 0.917)
p-value for RR		0.0381
OR - Odds Ratio (Zuranolone vs. Placebo)		0.18
95% CI for the OR		(0.038, 0.877)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.11
95% CI for the ARR		(-0.209, -0.018)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

5.1.2.2 .2 .8 PPD in der Anamnese

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders

History of PPD = 1st Episode

	Placebo (N=57)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	15 (26.3)	23 (33.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.29
95% CI for the RR		(0.744, 2.221)
p-value for RR		0.3685
OR - Odds Ratio (Zuranolone vs. Placebo)		1.43
95% CI for the OR		(0.660, 3.105)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.085, 0.235)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	4 (25.0)	4 (40.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.60
95% CI for the RR		(0.512, 4.996)
p-value for RR		0.4185
OR - Odds Ratio (Zuranolone vs. Placebo)		2.00
95% CI for the OR		(0.366, 10.919)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.15
95% CI for the ARR		(-0.220, 0.520)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

History of PPD = 1st Episode

	Placebo (N=57)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	11 (19.3)	12 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.91
95% CI for the RR		(0.437, 1.914)
p-value for RR		0.8124
OR - Odds Ratio (Zuranolone vs. Placebo)		0.90
95% CI for the OR		(0.362, 2.218)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.02
95% CI for the ARR		(-0.153, 0.120)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-201B - Safety Population

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Gastrointestinal disorders

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	3 (18.8)	2 (20.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.07
95% CI for the RR		(0.214, 5.311)
p-value for RR		0.9372
OR - Odds Ratio (Zuranolone vs. Placebo)		1.08
95% CI for the OR		(0.147, 7.959)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.301, 0.326)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-201B - Safety Population

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Infections and infestations

History of PPD = 1st Episode

	Placebo (N=57)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	4 (7.0)	12 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		2.51
95% CI for the RR		(0.858, 7.371)
p-value for RR		0.0928
OR - Odds Ratio (Zuranolone vs. Placebo)		2.84
95% CI for the OR		(0.862, 9.354)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.11
95% CI for the ARR		(-0.006, 0.219)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-201B - Safety Population

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Infections and infestations

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.31
95% CI for the RR		(0.016, 5.847)
p-value for RR		0.4338
OR - Odds Ratio (Zuranolone vs. Placebo)		0.28
95% CI for the OR		(0.012, 6.372)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.10
95% CI for the ARR		(-0.310, 0.107)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-201B - Safety Population

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Psychiatric disorders

History of PPD = 1st Episode

	Placebo (N=57)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	8 (14.0)	2 (2.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.21
95% CI for the RR		(0.046, 0.948)
p-value for RR		0.0424
OR - Odds Ratio (Zuranolone vs. Placebo)		0.19
95% CI for the OR		(0.038, 0.913)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.11
95% CI for the ARR		(-0.210, -0.012)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-201B - Safety Population

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Psychiatric disorders

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	2 (12.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.31
95% CI for the RR		(0.016, 5.847)
p-value for RR		0.4338
OR - Odds Ratio (Zuranolone vs. Placebo)		0.28
95% CI for the OR		(0.012, 6.372)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.10
95% CI for the ARR		(-0.310, 0.107)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOCs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-soc-201-by.sas:t-ae-soc-201-by-hist-safc.rtf **Run Date:** 25JUL2025

5.1.3 nach PT

5.1.3.1 ITT-Population

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-201B - Safety population

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Nervous system disorders/Somnolence

	Placebo (N=73)	Zuranolone (N=78)
Number of subjects with >=1 TEAE, n (%)	8 (11.0)	12 (15.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.40
95% CI for the RR		(0.609, 3.238)
p-value for RR		0.4263
OR - Odds Ratio (Zuranolone vs. Placebo)		1.48
95% CI for the OR		(0.567, 3.850)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.063, 0.152)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: Includes preferred term >=10% in any arm OR number of subjects with AE by PT with at least 10 subjects with the respective AE and >=1% in any arm. PT is presented in decreasing frequency of Zuranolone column.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-ovr.sas:t-ae-pt-201-ovr-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-201B - Safety population

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Nervous system disorders/Headache

	Placebo (N=73)	Zuranolone (N=78)
Number of subjects with >=1 TEAE, n (%)	9 (12.3)	7 (9.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.73
95% CI for the RR		(0.286, 1.854)
p-value for RR		0.5055
OR - Odds Ratio (Zuranolone vs. Placebo)		0.70
95% CI for the OR		(0.247, 1.991)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.132, 0.065)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: Includes preferred term >=10% in any arm OR number of subjects with AE by PT with at least 10 subjects with the respective AE and >=1% in any arm. PT is presented in decreasing frequency of Zuranolone column.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-ovr.sas:t-ae-pt-201-ovr-safc.rtf **Run Date:** 25JUL2025

5.1.3.2 Subgruppen

5.1.3.2 .1 Interaktionstest

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

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Nervous system disorders/ Somnolence

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	8 (11.0)	12 (15.4)	
Age Group (years)			
18 - 24, n / N (%)	3/25 (12.0)	1/17 (5.9)	0.2663
25 - 45, n / N (%)	5/48 (10.4)	11/61 (18.0)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	1/21 (4.8)	6/31 (19.4)	NA
>=28, n / N (%)	7/52 (13.5)	6/47 (12.8)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	3/32 (9.4)	8/31 (25.8)	NA
White, n / N (%)	5/39 (12.8)	3/45 (6.7)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes PT >=10% in any arm OR number of subjects with AE by PT with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-pt-201-int.sas:t-ae-pt-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

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Nervous system disorders/ Somnolence

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	3/13 (23.1)	1/16 (6.3)	0.0603
No, n / N (%)	5/60 (8.3)	11/62 (17.7)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	2/20 (10.0)	2/14 (14.3)	NA(a)
25-29.9, n / N (%)	2/19 (10.5)	2/22 (9.1)	NA(b)
>=30, n / N (%)	4/34 (11.8)	8/42 (19.0)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	5/31 (16.1)	8/33 (24.2)	NA
Postpartum, n / N (%)	3/42 (7.1)	4/45 (8.9)	
Family History of PPD			
Yes, n / N (%)	1/10 (10.0)	0/10	0.3403
No/Unknown, n / N (%)	7/63 (11.1)	12/68 (17.6)	

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).

NOTE 4: Includes PT >=10% in any arm OR number of subjects with AE by PT with at least 10 subjects with the respective AE and >=1% in any arm.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-int.sas:t-ae-pt-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

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Nervous system disorders/ Somnolence

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	7/57 (12.3)	11/68 (16.2)	0.9001
Recurrent Episode, n / N (%)	1/16 (6.3)	1/10 (10.0)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	1/8 (12.5)	1/10 (10.0)	NA
>=20, n / N (%)	7/65 (10.8)	11/68 (16.2)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes PT >=10% in any arm OR number of subjects with AE by PT with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-pt-201-int.sas:t-ae-pt-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

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Nervous system disorders/ Headache

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	9 (12.3)	7 (9.0)	
Age Group (years)			
18 - 24, n / N (%)	0/25	1/17 (5.9)	NA
25 - 45, n / N (%)	9/48 (18.8)	6/61 (9.8)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	1/21 (4.8)	3/31 (9.7)	NA
>=28, n / N (%)	8/52 (15.4)	4/47 (8.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	1/32 (3.1)	3/31 (9.7)	NA
White, n / N (%)	7/39 (17.9)	4/45 (8.9)	

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.

NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).

NOTE 4: Includes PT >=10% in any arm OR number of subjects with AE by PT with at least 10 subjects with the respective AE and >=1% in any arm.

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-int.sas:t-ae-pt-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

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Nervous system disorders/ Headache

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	1/13 (7.7)	1/16 (6.3)	NA
No, n / N (%)	8/60 (13.3)	6/62 (9.7)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	4/20 (20.0)	2/14 (14.3)	NA(a)
25-29.9, n / N (%)	1/19 (5.3)	1/22 (4.5)	NA(b)
>=30, n / N (%)	4/34 (11.8)	4/42 (9.5)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	2/31 (6.5)	3/33 (9.1)	NA
Postpartum, n / N (%)	7/42 (16.7)	4/45 (8.9)	
Family History of PPD			
Yes, n / N (%)	1/10 (10.0)	0/10	NA
No/Unknown, n / N (%)	8/63 (12.7)	7/68 (10.3)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes PT >=10% in any arm OR number of subjects with AE by PT with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-pt-201-int.sas:t-ae-pt-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

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Nervous system disorders/ Headache

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	6/57 (10.5)	7/68 (10.3)	NA
Recurrent Episode, n / N (%)	3/16 (18.8)	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	2/8 (25.0)	0/10	NA
>=20, n / N (%)	7/65 (10.8)	7/68 (10.3)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes PT >=10% in any arm OR number of subjects with AE by PT with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-pt-201-int.sas:t-ae-pt-201-int-safc.rtf **Run Date:** 25JUL2025

5.1.3.2 .2 Subgruppenanalysen

5.1.3.2 .2 .1 Alter

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Age Group: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

Age Group (years) = 18-24

	Placebo (N=25)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	3 (12.0)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.49
95% CI for the RR		(0.056, 4.326)
p-value for RR		0.5211
OR - Odds Ratio (Zuranolone vs. Placebo)		0.46
95% CI for the OR		(0.044, 4.820)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.06
95% CI for the ARR		(-0.231, 0.108)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-age-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Age Group: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

Age Group (years) = 25-45

	Placebo (N=48)	Zuranolone (N=61)
Number of subjects with >=1 TEAE, n (%)	5 (10.4)	11 (18.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.73
95% CI for the RR		(0.645, 4.646)
p-value for RR		0.2759
OR - Odds Ratio (Zuranolone vs. Placebo)		1.89
95% CI for the OR		(0.609, 5.875)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.053, 0.206)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-age-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Age Group: 217-PPD-201B - Safety Population

Page: 3 of 4

Nervous system disorders/Headache

Age Group (years) = 18-24

	Placebo (N=25)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		4.33
95% CI for the RR		(0.187, 100.486)
p-value for RR		0.3606
OR - Odds Ratio (Zuranolone vs. Placebo)		4.64
95% CI for the OR		(0.178, 120.771)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.06
95% CI for the ARR		(-0.074, 0.202)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-age-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Age Group: 217-PPD-201B - Safety Population

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Nervous system disorders/Headache

Age Group (years) = 25-45

	Placebo (N=48)	Zuranolone (N=61)
Number of subjects with >=1 TEAE, n (%)	9 (18.8)	6 (9.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.52
95% CI for the RR		(0.201, 1.372)
p-value for RR		0.1884
OR - Odds Ratio (Zuranolone vs. Placebo)		0.47
95% CI for the OR		(0.156, 1.437)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.222, 0.044)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-age-safc.rtf **Run Date:** 25JUL2025

5.1.3.2 .2 .2 Schwere der Erkrankung

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=21)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	1 (4.8)	6 (19.4)
RR - Relative Risk (Zuranolone vs. Placebo)		4.06
95% CI for the RR		(0.527, 31.360)
p-value for RR		0.1786
OR - Odds Ratio (Zuranolone vs. Placebo)		4.80
95% CI for the OR		(0.533, 43.196)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.15
95% CI for the ARR		(-0.020, 0.312)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=52)	Zuranolone (N=47)
Number of subjects with >=1 TEAE, n (%)	7 (13.5)	6 (12.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.95
95% CI for the RR		(0.343, 2.621)
p-value for RR		0.9185
OR - Odds Ratio (Zuranolone vs. Placebo)		0.94
95% CI for the OR		(0.292, 3.030)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.140, 0.126)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Nervous system disorders/Headache

Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=21)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	1 (4.8)	3 (9.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.03
95% CI for the RR		(0.226, 18.238)
p-value for RR		0.5265
OR - Odds Ratio (Zuranolone vs. Placebo)		2.14
95% CI for the OR		(0.207, 22.130)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.089, 0.187)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Nervous system disorders/Headache

Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

	Placebo (N=52)	Zuranolone (N=47)
Number of subjects with >=1 TEAE, n (%)	8 (15.4)	4 (8.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.55
95% CI for the RR		(0.178, 1.719)
p-value for RR		0.3060
OR - Odds Ratio (Zuranolone vs. Placebo)		0.51
95% CI for the OR		(0.143, 1.825)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.07
95% CI for the ARR		(-0.195, 0.058)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

5.1.3.2 .2 .3 Abstammung

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Race Group: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

Race Group = Black or African American

	Placebo (N=32)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	3 (9.4)	8 (25.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.75
95% CI for the RR		(0.803, 9.432)
p-value for RR		0.1071
OR - Odds Ratio (Zuranolone vs. Placebo)		3.36
95% CI for the OR		(0.800, 14.125)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.16
95% CI for the ARR		(-0.020, 0.349)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-race-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Race Group: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

Race Group = White

	Placebo (N=39)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	5 (12.8)	3 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.52
95% CI for the RR		(0.133, 2.037)
p-value for RR		0.3480
OR - Odds Ratio (Zuranolone vs. Placebo)		0.49
95% CI for the OR		(0.108, 2.179)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.06
95% CI for the ARR		(-0.189, 0.066)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-race-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Race Group: 217-PPD-201B - Safety Population

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Nervous system disorders/Headache

Race Group = Black or African American

	Placebo (N=32)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	1 (3.1)	3 (9.7)
RR - Relative Risk (Zuranolone vs. Placebo)		3.10
95% CI for the RR		(0.340, 28.190)
p-value for RR		0.3158
OR - Odds Ratio (Zuranolone vs. Placebo)		3.32
95% CI for the OR		(0.326, 33.803)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.055, 0.186)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-race-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Race Group: 217-PPD-201B - Safety Population

Nervous system disorders/Headache
Race Group = White

	Placebo (N=39)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	7 (17.9)	4 (8.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.50
95% CI for the RR		(0.157, 1.566)
p-value for RR		0.2315
OR - Odds Ratio (Zuranolone vs. Placebo)		0.45
95% CI for the OR		(0.120, 1.657)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.237, 0.056)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-race-safc.rtf **Run Date:** 25JUL2025

5.1.3.2 .2 .4 Antidepressiva-Nutzung

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of subjects with >=1 TEAE, n (%)	3 (23.1)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.27
95% CI for the RR		(0.032, 2.306)
p-value for RR		0.2319
OR - Odds Ratio (Zuranolone vs. Placebo)		0.22
95% CI for the OR		(0.020, 2.451)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.17
95% CI for the ARR		(-0.426, 0.090)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-adt-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

Antidepressant Use at Baseline = No

	Placebo (N=60)	Zuranolone (N=62)
Number of subjects with >=1 TEAE, n (%)	5 (8.3)	11 (17.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.13
95% CI for the RR		(0.787, 5.763)
p-value for RR		0.1369
OR - Odds Ratio (Zuranolone vs. Placebo)		2.37
95% CI for the OR		(0.771, 7.298)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(-0.024, 0.212)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-adt-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

Page: 3 of 4

Nervous system disorders/Headache

Antidepressant Use at Baseline = Yes

	Placebo (N=13)	Zuranolone (N=16)
Number of subjects with >=1 TEAE, n (%)	1 (7.7)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.81
95% CI for the RR		(0.056, 11.773)
p-value for RR		0.8790
OR - Odds Ratio (Zuranolone vs. Placebo)		0.80
95% CI for the OR		(0.045, 14.164)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.202, 0.173)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-adt-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Nervous system disorders/Headache

Antidepressant Use at Baseline = No

	Placebo (N=60)	Zuranolone (N=62)
Number of subjects with >=1 TEAE, n (%)	8 (13.3)	6 (9.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.73
95% CI for the RR		(0.268, 1.967)
p-value for RR		0.5288
OR - Odds Ratio (Zuranolone vs. Placebo)		0.70
95% CI for the OR		(0.226, 2.143)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.04
95% CI for the ARR		(-0.150, 0.077)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-adt-safc.rtf **Run Date:** 25JUL2025

5.1.3.2 .2 .5 BMI

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=20)	Zuranolone (N=14)
Number of subjects with >=1 TEAE, n (%)	2 (10.0)	2 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.43
95% CI for the RR		(0.228, 8.969)
p-value for RR		0.7036
OR - Odds Ratio (Zuranolone vs. Placebo)		1.50
95% CI for the OR		(0.185, 12.147)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.183, 0.268)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=19)	Zuranolone (N=22)
Number of subjects with >=1 TEAE, n (%)	2 (10.5)	2 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.86
95% CI for the RR		(0.134, 5.555)
p-value for RR		0.8773
OR - Odds Ratio (Zuranolone vs. Placebo)		0.85
95% CI for the OR		(0.108, 6.695)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.197, 0.169)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of subjects with >=1 TEAE, n (%)	4 (11.8)	8 (19.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.62
95% CI for the RR		(0.533, 4.922)
p-value for RR		0.3956
OR - Odds Ratio (Zuranolone vs. Placebo)		1.76
95% CI for the OR		(0.483, 6.454)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.088, 0.234)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

Nervous system disorders/Headache

BMI (kg/m^2) Group 2 = <=24.9

	Placebo (N=20)	Zuranolone (N=14)
Number of subjects with >=1 TEAE, n (%)	4 (20.0)	2 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.71
95% CI for the RR		(0.151, 3.379)
p-value for RR		0.6713
OR - Odds Ratio (Zuranolone vs. Placebo)		0.67
95% CI for the OR		(0.104, 4.261)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.06
95% CI for the ARR		(-0.311, 0.196)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

Nervous system disorders/Headache
BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=19)	Zuranolone (N=22)
Number of subjects with >=1 TEAE, n (%)	1 (5.3)	1 (4.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.86
95% CI for the RR		(0.058, 12.889)
p-value for RR		0.9153
OR - Odds Ratio (Zuranolone vs. Placebo)		0.86
95% CI for the OR		(0.050, 14.706)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.140, 0.126)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.
Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

Nervous system disorders/Headache

BMI (kg/m^2) Group 2 = >=30

	Placebo (N=34)	Zuranolone (N=42)
Number of subjects with >=1 TEAE, n (%)	4 (11.8)	4 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.81
95% CI for the RR		(0.218, 3.000)
p-value for RR		0.7519
OR - Odds Ratio (Zuranolone vs. Placebo)		0.79
95% CI for the OR		(0.182, 3.421)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.02
95% CI for the ARR		(-0.162, 0.118)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

5.1.3.2 .2 .6 Beginn der PPD

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Onset of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	5 (16.1)	8 (24.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.50
95% CI for the RR		(0.551, 4.102)
p-value for RR		0.4264
OR - Odds Ratio (Zuranolone vs. Placebo)		1.66
95% CI for the OR		(0.479, 5.779)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.114, 0.276)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-onset-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Onset of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

Onset of PPD = Postpartum

	Placebo (N=42)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	3 (7.1)	4 (8.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.24
95% CI for the RR		(0.296, 5.235)
p-value for RR		0.7654
OR - Odds Ratio (Zuranolone vs. Placebo)		1.27
95% CI for the OR		(0.267, 6.035)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.096, 0.131)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-onset-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Onset of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders/Headache

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	2 (6.5)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.41
95% CI for the RR		(0.252, 7.875)
p-value for RR		0.6961
OR - Odds Ratio (Zuranolone vs. Placebo)		1.45
95% CI for the OR		(0.226, 9.320)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.104, 0.157)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-onset-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Onset of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders/Headache

Onset of PPD = Postpartum

	Placebo (N=42)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	7 (16.7)	4 (8.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.53
95% CI for the RR		(0.168, 1.692)
p-value for RR		0.2858
OR - Odds Ratio (Zuranolone vs. Placebo)		0.49
95% CI for the OR		(0.132, 1.805)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.08
95% CI for the ARR		(-0.218, 0.062)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-onset-safc.rtf **Run Date:** 25JUL2025

5.1.3.2 .2 .7 PPD in der Familie

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Family History of PPD: 217-PPD-201B - Safety Population

Page: 1 of 4

Nervous system disorders/Somnolence

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.015, 7.323)
p-value for RR		0.4858
OR - Odds Ratio (Zuranolone vs. Placebo)		0.30
95% CI for the OR		(0.011, 8.332)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.328, 0.146)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Family History of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders/Somnolence

Family History of PPD = No/Unknown

	Placebo (N=63)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	7 (11.1)	12 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.59
95% CI for the RR		(0.667, 3.779)
p-value for RR		0.2956
OR - Odds Ratio (Zuranolone vs. Placebo)		1.71
95% CI for the OR		(0.629, 4.674)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.054, 0.185)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Family History of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders/Headache

Family History of PPD = Yes

	Placebo (N=10)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	1 (10.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.015, 7.323)
p-value for RR		0.4858
OR - Odds Ratio (Zuranolone vs. Placebo)		0.30
95% CI for the OR		(0.011, 8.332)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.328, 0.146)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Family History of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders/Headache

Family History of PPD = No/Unknown

	Placebo (N=63)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	8 (12.7)	7 (10.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.81
95% CI for the RR		(0.312, 2.106)
p-value for RR		0.6665
OR - Odds Ratio (Zuranolone vs. Placebo)		0.79
95% CI for the OR		(0.268, 2.318)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.02
95% CI for the ARR		(-0.133, 0.085)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

5.1.3.2 .2 .8 PPD in der Anamnese

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by History of PPD: 217-PPD-201B - Safety Population

Page: 1 of 4

Nervous system disorders/Somnolence

History of PPD = 1st Episode

	Placebo (N=57)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	7 (12.3)	11 (16.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.32
95% CI for the RR		(0.546, 3.175)
p-value for RR		0.5394
OR - Odds Ratio (Zuranolone vs. Placebo)		1.38
95% CI for the OR		(0.497, 3.826)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.083, 0.161)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-hist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by History of PPD: 217-PPD-201B - Safety Population

Page: 2 of 4

Nervous system disorders/Somnolence

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	1 (6.3)	1 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.60
95% CI for the RR		(0.112, 22.801)
p-value for RR		0.7288
OR - Odds Ratio (Zuranolone vs. Placebo)		1.67
95% CI for the OR		(0.092, 30.060)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.183, 0.258)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-hist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by History of PPD: 217-PPD-201B - Safety Population

Page: 3 of 4

Nervous system disorders/Headache

History of PPD = 1st Episode

	Placebo (N=57)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	6 (10.5)	7 (10.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.98
95% CI for the RR		(0.348, 2.745)
p-value for RR		0.9662
OR - Odds Ratio (Zuranolone vs. Placebo)		0.98
95% CI for the OR		(0.308, 3.087)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.110, 0.105)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-hist-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by History of PPD: 217-PPD-201B - Safety Population

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Nervous system disorders/Headache

History of PPD = Recurrent Episode

	Placebo (N=16)	Zuranolone (N=10)
Number of subjects with >=1 TEAE, n (%)	3 (18.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.22
95% CI for the RR		(0.013, 3.872)
p-value for RR		0.3013
OR - Odds Ratio (Zuranolone vs. Placebo)		0.18
95% CI for the OR		(0.009, 3.961)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.16
95% CI for the ARR		(-0.389, 0.068)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PTs are consistent with the main analysis table and are ordered by decreasing frequency in the Zuranolone group.

Source: biib125/v_a/germany_amnog/t-ae-pt-201-by.sas:t-ae-pt-201-by-hist-safc.rtf **Run Date:** 25JUL2025

5.2 Schwere UE

5.2.1 Gesamtraten

5.2.1.1 ITT-Population

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity: 217-PPD-201B - Safety population

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Grade 3/4/5

	Placebo (N=73)	Zuranolone (N=78)
Number of subjects with >=1 TEAE, n (%)	3 (4.1)	3 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.94
95% CI for the RR		(0.195, 4.490)
p-value for RR		0.9340
OR - Odds Ratio (Zuranolone vs. Placebo)		0.93
95% CI for the OR		(0.182, 4.778)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.065, 0.060)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.
Source: biib125/v_a/germany_amnog/t-ae-gr-201-ovr.sas:t-ae-gr-201-ovr-safc.rtf **Run Date:** 25JUL2025

5.2.1.2 Subgruppen

5.2.1.2 .1 Interaktionstest

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

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Grade >=3

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	3 (4.1)	3 (3.8)	
Age Group (years)			
18 - 24, n / N (%)	1/25 (4.0)	1/17 (5.9)	NA
25 - 45, n / N (%)	2/48 (4.2)	2/61 (3.3)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	1/21 (4.8)	1/31 (3.2)	NA
>=28, n / N (%)	2/52 (3.8)	2/47 (4.3)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	2/32 (6.3)	2/31 (6.5)	NA
White, n / N (%)	1/39 (2.6)	1/45 (2.2)	
Antidepressant Use at Baseline			
Yes, n / N (%)	2/13 (15.4)	1/16 (6.3)	NA
No, n / N (%)	1/60 (1.7)	2/62 (3.2)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-gr-201-int.sas:t-ae-gr-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

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Grade >=3

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	1/20 (5.0)	1/14 (7.1)	NA(a)
25-29.9, n / N (%)	1/19 (5.3)	0/22	NA(b)
>=30, n / N (%)	1/34 (2.9)	2/42 (4.8)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	0/31	0/33	NA
Postpartum, n / N (%)	3/42 (7.1)	3/45 (6.7)	
Family History of PPD			
Yes, n / N (%)	0/10	0/10	NA
No/Unknown, n / N (%)	3/63 (4.8)	3/68 (4.4)	
History of PPD			
1st Episode, n / N (%)	3/57 (5.3)	3/68 (4.4)	NA
Recurrent Episode, n / N (%)	0/16	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/8	0/10	NA
>=20, n / N (%)	3/65 (4.6)	3/68 (4.4)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).

(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-gr-201-int.sas:t-ae-gr-201-int-safc.rtf **Run Date:** 25JUL2025

5.2.1.2 .2 Subgruppenanalysen

5.2.1.2 .2 .1 Alter

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Age Group: 217-PPD-201B - Safety Population

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Age Group (years) = 18-24

Grade 3/4/5

	Placebo (N=25)	**Zuranolone (N=17)**
Number of subjects with >=1 TEAE, n (%)	1 (4.0)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.47
95% CI for the RR		(0.099, 21.936)
p-value for RR		0.7797
OR - Odds Ratio (Zuranolone vs. Placebo)		1.50
95% CI for the OR		(0.087, 25.753)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.117, 0.155)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-age-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Age Group: 217-PPD-201B - Safety Population

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Age Group (years) = 25-45

Grade 3/4/5

	Placebo (N=48)	Zuranolone (N=61)
Number of subjects with >=1 TEAE, n (%)	2 (4.2)	2 (3.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.79
95% CI for the RR		(0.115, 5.384)
p-value for RR		0.8070
OR - Odds Ratio (Zuranolone vs. Placebo)		0.78
95% CI for the OR		(0.106, 5.747)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.081, 0.063)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-age-safc.rtf **Run Date:** 25JUL2025

5.2.1.2 .2 .2 Schwere der Erkrankung

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Baseline HAMD-17 Total Score Category < 28 (Median of Baseline HAM-D Total Score)
Grade 3/4/5

	Placebo (N=21)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	1 (4.8)	1 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.68
95% CI for the RR		(0.045, 10.241)
p-value for RR		0.7787
OR - Odds Ratio (Zuranolone vs. Placebo)		0.67
95% CI for the OR		(0.039, 11.285)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.02
95% CI for the ARR		(-0.126, 0.095)

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.
Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Baseline HAMD-17 Total Score: 217-PPD-201B - Safety Population

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Baseline HAMD-17 Total Score Category >= 28 (Median of Baseline HAM-D Total Score)

Grade 3/4/5

	Placebo (N=52)	Zuranolone (N=47)
Number of subjects with >=1 TEAE, n (%)	2 (3.8)	2 (4.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.11
95% CI for the RR		(0.162, 7.546)
p-value for RR		0.9178
OR - Odds Ratio (Zuranolone vs. Placebo)		1.11
95% CI for the OR		(0.150, 8.218)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.074, 0.082)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-hamd-safc.rtf **Run Date:** 25JUL2025

5.2.1.2 .2 .3 Abstammung

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Race Group: 217-PPD-201B - Safety Population

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Race Group = Black or African American

Grade 3/4/5

	Placebo (N=32)	Zuranolone (N=31)
Number of subjects with >=1 TEAE, n (%)	2 (6.3)	2 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.03
95% CI for the RR		(0.155, 6.879)
p-value for RR		0.9738
OR - Odds Ratio (Zuranolone vs. Placebo)		1.03
95% CI for the OR		(0.136, 7.840)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.118, 0.122)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-race-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Race Group: 217-PPD-201B - Safety Population

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Race Group = White

Grade 3/4/5

	Placebo (N=39)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	1 (2.6)	1 (2.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.87
95% CI for the RR		(0.056, 13.401)
p-value for RR		0.9184
OR - Odds Ratio (Zuranolone vs. Placebo)		0.86
95% CI for the OR		(0.052, 14.282)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.069, 0.062)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-race-safc.rtf **Run Date:** 25JUL2025

5.2.1.2 .2 .4 Antidepressiva-Nutzung

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Antidepressant Use at Baseline = Yes

Grade 3/4/5

	Placebo (N=13)	Zuranolone (N=16)
Number of subjects with >=1 TEAE, n (%)	2 (15.4)	1 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.41
95% CI for the RR		(0.041, 3.996)
p-value for RR		0.4400
OR - Odds Ratio (Zuranolone vs. Placebo)		0.37
95% CI for the OR		(0.029, 4.573)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.321, 0.138)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-adt-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Baseline Antidepressant Use: 217-PPD-201B - Safety Population

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Antidepressant Use at Baseline = No

Grade 3/4/5

	Placebo (N=60)	Zuranolone (N=62)
Number of subjects with >=1 TEAE, n (%)	1 (1.7)	2 (3.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.94
95% CI for the RR		(0.180, 20.789)
p-value for RR		0.5856
OR - Odds Ratio (Zuranolone vs. Placebo)		1.97
95% CI for the OR		(0.174, 22.277)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.039, 0.070)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-adt-safc.rtf **Run Date:** 25JUL2025

5.2.1.2 .2 .5 BMI

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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BMI (kg/m^2) Group 2 = <=24.9

Grade 3/4/5

	Placebo (N=20)	Zuranolone (N=14)
Number of subjects with >=1 TEAE, n (%)	1 (5.0)	1 (7.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.43
95% CI for the RR		(0.097, 20.968)
p-value for RR		0.7947
OR - Odds Ratio (Zuranolone vs. Placebo)		1.46
95% CI for the OR		(0.084, 25.525)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.144, 0.187)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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BMI (kg/m^2) Group 2 = 25-29.9

Grade 3/4/5

	Placebo (N=19)	Zuranolone (N=22)
Number of subjects with >=1 TEAE, n (%)	1 (5.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.29
95% CI for the RR		(0.012, 6.724)
p-value for RR		0.4401
OR - Odds Ratio (Zuranolone vs. Placebo)		0.27
95% CI for the OR		(0.011, 7.134)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.05
95% CI for the ARR		(-0.183, 0.077)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Baseline BMI (kg/m^2) Group: 217-PPD-201B - Safety Population

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BMI (kg/m^2) Group 2 = >=30

Grade 3/4/5

	Placebo (N=34)	Zuranolone (N=42)
Number of subjects with >=1 TEAE, n (%)	1 (2.9)	2 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.62
95% CI for the RR		(0.153, 17.104)
p-value for RR		0.6887
OR - Odds Ratio (Zuranolone vs. Placebo)		1.65
95% CI for the OR		(0.143, 19.012)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.068, 0.104)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-bmi-safc.rtf **Run Date:** 25JUL2025

5.2.1.2 .2 .6 Beginn der PPD

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Onset of PPD: 217-PPD-201B - Safety Population

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Onset of PPD = Postpartum

Grade 3/4/5

	Placebo (N=42)	Zuranolone (N=45)
Number of subjects with >=1 TEAE, n (%)	3 (7.1)	3 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.93
95% CI for the RR		(0.199, 4.371)
p-value for RR		0.9302
OR - Odds Ratio (Zuranolone vs. Placebo)		0.93
95% CI for the OR		(0.177, 4.877)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.111, 0.102)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-onset-safc.rtf **Run Date:** 25JUL2025

5.2.1.2 .2 .7 PPD in der Familie

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Family History of PPD: 217-PPD-201B - Safety Population

Page: 5 of 5

Family History of PPD = No/Unknown

Grade 3/4/5

	Placebo (N=63)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	3 (4.8)	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.93
95% CI for the RR		(0.194, 4.423)
p-value for RR		0.9237
OR - Odds Ratio (Zuranolone vs. Placebo)		0.92
95% CI for the OR		(0.179, 4.751)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.075, 0.068)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-fhist-safc.rtf **Run Date:** 25JUL2025

5.2.1.2 .2 .8 PPD in der Anamnese

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by History of PPD: 217-PPD-201B - Safety Population

Page: 3 of 5

History of PPD = 1st Episode

Grade 3/4/5

	Placebo (N=57)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	3 (5.3)	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.84
95% CI for the RR		(0.176, 3.993)
p-value for RR		0.8247
OR - Odds Ratio (Zuranolone vs. Placebo)		0.83
95% CI for the OR		(0.161, 4.285)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.084, 0.067)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.

Source: biib125/v_a/germany_amnog/t-ae-gr-201-by.sas:t-ae-gr-201-by-hist-safc.rtf **Run Date:** 25JUL2025

5.2.2 nach SOC

5.2.2.1 ITT-Population

Number of Subjects with Grade >=3 Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-201B - Safety population

Page: 1 of 1

No data to report

	Placebo (N=73)	Zuranolone (N=78)
Criteria are not met for subgroup analysis		

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.
NOTE 3: Includes system organ class >=5% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm. SOC is presented in decreasing frequency of Zuranolone column.
Source: biib125/v_a/germany_amnog/t-ae-gr3-soc-201-ovr.sas:t-ae-gr3-soc-201-ovr-safc.rtf **Run Date:** 25JUL2025

5.2.2.2 Subgruppen

5.2.2.2 .1 Interaktionstest

Number of Subjects with Grade >=3 Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

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THERE ARE NO SUBJECTS THAT MEET THIS CRITERIA.

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes SOC >=5% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-gr3-soc-201-int.sas:t-ae-gr3-soc-201-int-safc.rtf **Run Date:** 25JUL2025

5.2.2.2 .2 Subgruppenanalysen

Nicht zutreffend.

5.2.3 nach PT

5.2.3.1 ITT-Population

Number of Subjects with Grade >=3 Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-201B - Safety population

Page: 1 of 1

No data to report

	Placebo (N=73)	Zuranolone (N=78)
Criteria are not met for subgroup analysis		

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: AE severity grade is derived based on the AE severity collected: Mild is classified as Grade 1, Moderate as Grade 2, and Severe as Grade 3 or higher.
NOTE 3: Includes preferred term >=5% in any arm OR number of subjects with AE by PT with at least 10 subjects with the respective AE and >=1% in any arm. PT is presented in decreasing frequency of Zuranolone column.
Source: biib125/v_a/germany_amnog/t-ae-gr3-pt-201-ovr.sas:t-ae-gr3-pt-201-ovr-safc.rtf **Run Date:** 25JUL2025

5.2.3.2 Subgruppen

5.2.3.2 .1 Interaktionstest

Number of Subjects with Grade >=3 Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

Page: 1 of 1

THERE ARE NO SUBJECTS THAT MEET THIS CRITERIA.

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes PT >=5% in any arm OR number of subjects with AE by PT with at least 10 subjects with the respective AE and >=1% in any arm.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-gr3-pt-201-int.sas:t-ae-gr3-pt-201-int-safc.rtf **Run Date:** 25JUL2025

5.2.3.2 .2 Subgruppenanalysen

Nicht zutreffend.

5.3 SUE

5.3.1 Gesamtraten

5.3.1.1 ITT-Population

Number of Subjects with at Least One Serious Treatment-Emergent Adverse Event: 217-PPD-201B - Safety population

Page: 1 of 1

	Placebo (N=73)	Zuranolone (N=78)
Number of subjects with >=1 TEAE, n (%)	1 (1.4)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.94
95% CI for the RR		(0.060, 14.689)
p-value for RR		0.9624
OR - Odds Ratio (Zuranolone vs. Placebo)		0.94
95% CI for the OR		(0.057, 15.229)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.037, 0.036)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-sae-201-ovr.sas:t-sae-201-ovr-safc.rtf **Run Date:** 25JUL2025

5.3.1.2 Subgruppen

5.3.1.2 .1 Interaktionstest

Number of Subjects with at Least One Serious Treatment-Emergent Adverse Event: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	1 (1.4)	1 (1.3)	
Age Group (years)			
18 - 24, n / N (%)	0/25	1/17 (5.9)	NA
25 - 45, n / N (%)	1/48 (2.1)	0/61	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	1/21 (4.8)	0/31	NA
>=28, n / N (%)	0/52	1/47 (2.1)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	0/32	1/31 (3.2)	NA
White, n / N (%)	1/39 (2.6)	0/45	
Antidepressant Use at Baseline			
Yes, n / N (%)	1/13 (7.7)	0/16	NA
No, n / N (%)	0/60	1/62 (1.6)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sae-201-int.sas:t-sae-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with at Least One Serious Treatment-Emergent Adverse Event: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	0/20	1/14 (7.1)	NA(a)
25-29.9, n / N (%)	0/19	0/22	NA(b)
>=30, n / N (%)	1/34 (2.9)	0/42	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	0/31	0/33	NA
Postpartum, n / N (%)	1/42 (2.4)	1/45 (2.2)	
Family History of PPD			
Yes, n / N (%)	0/10	0/10	NA
No/Unknown, n / N (%)	1/63 (1.6)	1/68 (1.5)	
History of PPD			
1st Episode, n / N (%)	1/57 (1.8)	1/68 (1.5)	NA
Recurrent Episode, n / N (%)	0/16	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	1/8 (12.5)	0/10	NA
>=20, n / N (%)	0/65	1/68 (1.5)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sae-201-int.sas:t-sae-201-int-safc.rtf **Run Date:** 25JUL2025

5.3.1.2 .2 Subgruppenanalysen

Nicht zutreffend.

5.3.2 nach SOC

5.3.2.1 ITT-Population

Number of Subjects with Serious Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-201B - Safety population

Page: 1 of 1

No data to report

	Placebo (N=73)	Zuranolone (N=78)
Criteria are not met for subgroup analysis		

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: Includes system organ class >=5% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm. SOC is presented in decreasing frequency of Zuranolone column.

Source: biib125/v_a/germany_amnog/t-sae-soc-201-ovr.sas:t-sae-soc-201-ovr-safc.rtf **Run Date:** 25JUL2025

5.3.2.2 Subgruppen

5.3.2.2 .1 Interaktionstest

Number of Subjects with Serious Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

Page: 1 of 1

THERE ARE NO SUBJECTS THAT MEET THIS CRITERIA.

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes SOC >=5% in any arm OR number of subjects with AE by SOC with at least 10 subjects with the respective AE and >=1% in any arm. SOC is presented in decreasing frequency of Zuranolone column.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sae-soc-201-int.sas:t-sae-soc-201-int-safc.rtf **Run Date:** 25JUL2025

5.3.2.2 .2 Subgruppenanalysen

Nicht zutreffend.

5.3.3 nach PT

5.3.3.1 ITT-Population

Number of Subjects with Serious Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-201B - Safety population

Page: 1 of 1

No data to report

	Placebo (N=73)	Zuranolone (N=78)
Criteria are not met for subgroup analysis		

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: Includes preferred term >=5% in any arm OR number of subjects with AE by PT with at least 10 subjects with the respective AE and >=1% in any arm. PT is presented in decreasing frequency of Zuranolone column.
Source: biib125/v_a/germany_amnog/t-sae-pt-201-ovr.sas:t-sae-pt-201-ovr-safc.rtf **Run Date:** 25JUL2025

5.3.3.2 Subgruppen

5.3.3.2 .1 Interaktionstest

Number of Subjects with Serious Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-201B - Safety population

Page: 1 of 1

THERE ARE NO SUBJECTS THAT MEET THIS CRITERIA.

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
NOTE 4: Includes PT >=5% in any arm OR number of subjects with AE by PT with at least 10 subjects with the respective AE and >=1% in any arm. SOC is presented in decreasing frequency of Zuranolone column.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-sae-pt-201-int.sas:t-sae-pt-201-int-safc.rtf **Run Date:** 25JUL2025

5.3.3.2 .2 Subgruppenanalysen

Nicht zutreffend.

5.4 Therapieabbruch aufgrund von UE

5.4.1 Gesamtraten

5.4.1.1 ITT-Population

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event: 217-PPD-201B - Safety population

Page: 1 of 1

	Placebo (N=73)	Zuranolone (N=78)
Number of subjects with >=1 TEAE, n (%)	0	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.81
95% CI for the RR		(0.116, 67.904)
p-value for RR		0.5249
OR - Odds Ratio (Zuranolone vs. Placebo)		2.85
95% CI for the OR		(0.114, 70.959)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.023, 0.048)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-disc-201-ovr.sas:t-ae-disc-201-ovr-safc.rtf **Run Date:** 25JUL2025

5.4.1.2 Subgruppen

5.4.1.2 .1 Interaktionstest

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	0	1 (1.3)	
Age Group (years)			
18 - 24, n / N (%)	0/25	0/17	NA
25 - 45, n / N (%)	0/48	1/61 (1.6)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	0/21	1/31 (3.2)	NA
>=28, n / N (%)	0/52	0/47	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	0/32	0/31	NA
White, n / N (%)	0/39	1/45 (2.2)	
Antidepressant Use at Baseline			
Yes, n / N (%)	0/13	1/16 (6.3)	NA
No, n / N (%)	0/60	0/62	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-disc-201-int.sas:t-ae-disc-201-int-safc.rtf **Run Date:** 25JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event: Treatment by Subgroup Interaction: 217-PPD-201B - Safety Population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=73)	Zuranolone (N=78)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	0/20	0/14	NA(a)
25-29.9, n / N (%)	0/19	0/22	NA(b)
>=30, n / N (%)	0/34	1/42 (2.4)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	0/31	0/33	NA
Postpartum, n / N (%)	0/42	1/45 (2.2)	
Family History of PPD			
Yes, n / N (%)	0/10	0/10	NA
No/Unknown, n / N (%)	0/63	1/68 (1.5)	
History of PPD			
1st Episode, n / N (%)	0/57	1/68 (1.5)	NA
Recurrent Episode, n / N (%)	0/16	0/10	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/8	0/10	NA
>=20, n / N (%)	0/65	1/68 (1.5)	

NOTE 1: AEs were coded using MedDRA version 24.0.
NOTE 2: If there is no event for at least one category in treatment*subgroup combination, p-value is based on relative risk normal approximation after adding 0.5 to all counts of each treatment*subgroup combination. Otherwise, p-value is based on the generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, treatment, subgroup, and subgroup-by-treatment interaction with "Log" link function. NA indicates criteria not met for subgroup/interaction analysis.
NOTE 3: n / N (%) = number of subjects with the AE specified in the subgroup / number of subjects in the subgroup and (n / N *100%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=24.9 vs 25-29.9, <=24.9 vs >=30, and 25-29.9 vs >=30 respectively.
Source: biib125/v_a/germany_amnog/t-ae-disc-201-int.sas:t-ae-disc-201-int-safc.rtf **Run Date:** 25JUL2025

5.4.1.2 .2 Subgruppenanalysen

Nicht zutreffend.

5.4.2 nach SOC

5.4.2.1 ITT-Population

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-201B - Safety population

Page: 1 of 1

Nervous system disorders

	Placebo (N=73)	Zuranolone (N=78)
Number of subjects with >=1 TEAE, n (%)	0	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.81
95% CI for the RR		(0.116, 67.904)
p-value for RR		0.5249
OR - Odds Ratio (Zuranolone vs. Placebo)		2.85
95% CI for the OR		(0.114, 70.959)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.023, 0.048)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: SOC is presented in decreasing frequency of Zuranolone column.

Source: biib125/v_a/germany_amnog/t-ae-disc-soc-201-ovr.sas:t-ae-disc-soc-201-ovr-safc.rtf **Run Date:** 25JUL2025

5.4.2.2 Subgruppen

5.4.2.2 .1 Interaktionstest

Nicht zutreffend.

5.4.2.2 .2 Subgruppenanalysen

Nicht zutreffend.

5.4.3 nach PT

5.4.3.1 ITT-Population

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-201B - Safety population

Page: 1 of 1

Nervous system disorders/Sedation

	Placebo (N=73)	Zuranolone (N=78)
Number of subjects with >=1 TEAE, n (%)	0	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.81
95% CI for the RR		(0.116, 67.904)
p-value for RR		0.5249
OR - Odds Ratio (Zuranolone vs. Placebo)		2.85
95% CI for the OR		(0.114, 70.959)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.023, 0.048)

NOTE 1: AEs were coded using MedDRA version 24.0.

NOTE 2: PT is presented in decreasing frequency of Zuranolone column.

Source: biib125/v_a/germany_amnog/t-ae-disc-pt-201-ovr.sas:t-ae-disc-pt-201-ovr-safc.rtf **Run Date:** 25JUL2025

5.4.3.2 Subgruppen

5.4.3.2 .1 Interaktionstest

Nicht zutreffend.

5.4.3.2 .2 Subgruppenanalysen

Nicht zutreffend.